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Pharmaceutical Co.

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SMART
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Select the
Desired Option:

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Products

Certificates

Pipeline

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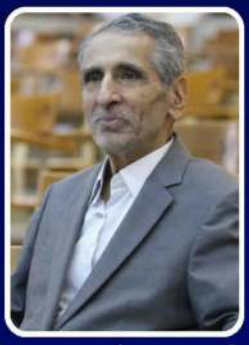

Parsian pharma group at first was inspired by the dedication, mentoring, and leadership of late Professor Dr. Abbas Shafiee. Parsian Pharmaceutical Company was established in 2009 in Avicenna National Biotechnology Park with the aim of meeting the domestic market need for high-tech Active Pharmaceutical Ingredients by relying on collaborative knowledge and hands-on experience of accomplished scientific members of pharmaceutical department of University of Tehran.

By adopting cutting-edge technologies and accurate strategies in various facets of providing affordable APIs for meeting domestic needs, Parsian Pharmaceutical Company has turned into one of the most credible rock stones for each and every one of the pharmaceutical companies seeking for API's synthesized by high-end facilities and broad range of knowledge behind the process.

In 2015, Parsian Pharmaceutical Company succeeded to obtain two invaluable certificates—namely GMP Export and GMP Production Certificate—from Iranian Ministry of Health & Medical Education which is accordance with PIC/S guidelines—based on its visions and missions and after inspections by the experts of the Food and Drug Administration. Therefore, it named as the first and only company producing the hazardous Active Pharmaceutical Ingredient in accordance with the international certificates of Food and Drug Administration in Iran.

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In 2017, in order to increase the product portfolio and also increase the production volume, the company constructed a factory in Baharestan industrial zone. In this regard, the company designed and ordered the most up-to-date equipment in compliance with current world standards by considering the requirements for the production of Hazardous Active Pharmaceutical Products.

On the other hand, due to the requirements related to the production of Hazard products and the lack of sufficient facilities and equipment in companies producing the finished product, the company also put granule production on its agenda to reduce the concerns of finished-product-producing companies and facilitate the drug formulation process. Hence, to design and equip the production line of hazardous Active Pharmaceutical Ingredients, the granule production line was also designed and equipped. It is worth to mention that all of the hazardous lines of the company is designed and equipped with closed system which prevent any exposure to substances and can support manufacturing of hazardous substances to OEB 5. OEB 5-componds are active pharmaceutical ingredients that have been assigned to an occupational exposure band (OEB) rating of 5, or the most severe rating in a 5-band occupational exposure banding system.

Finally, in 2019, a new production site was put into operation and the company succeeded in obtaining Iranian GMP certificate on three production lines—that is—hazard, general, and granular active Pharmaceutical Ingredients from Iranian Food and Drug Administration.

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At present, Parsian Pharmaceutical Company has 141 staff with its 2500 sq. m^2 production plant including; 3 API Line,2 granulation line and one pilot and Kilo lab, has put wide portfolio of production on the agenda by relying on hands-on experiences of best scientists has been able to make the country self-sufficient.

TOTAL AREA 5554 sq m^2

LAND AREA 4200 sq m^2

Laboratory Area	sq m^2
Research Laboratory	490
Microbial Laboratory	160
Quality control laboratory	390
Manufacturing	1220

Also, by considering the knowledge-based nature of Parsian Pharmaceutical Company and based on the main mission of the company, which is the focus on Research and Development and offering new products to the market of Active Pharmaceutical Ingredients and granules, the company has more than 20 active projects in the Research and Development and analysis phase to be investigated and industrialized, which will be launched to the market based on priorities and needs after meeting the necessary standards.

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Our **Customers**

Meeting domestic need for API & Granule

Parsian pharmaceutical company implements numerous cooperation projects with leading pharmaceutical companies throughout Iran for meeting the domestic pharmaceutical industries need for high-tech active pharmaceutical ingredients (APIs) and granules i.e. General API, Hazardous API and Hazardous granule with cutting-edged technology and high standards, as one of the most evolved industries in Iran.
In these years of activities, Parsian pharmaceutical company has been cooperating in the transfer of technologies for synthesizing and production of any kind of novel active pharmaceutical ingredients (APIs) and granules in Iran.

Features and capabilities

Parsian's production lines comply with Iranian GMP standards, and one of the key distinguishing strengths of Parsian pharmaceutical company is that it has obtained export good manufacturing practice (Export GMP) certificate for all of production lines of General API, Hazardous API and Hazardous granule from the ministry of health and medical education of Islamic republic of Iran and food and drug organization of Iran (I FDA), in 2021.

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Our **Customers**

Features and capabilities

Parsian pharmaceutical Co has obtained numerous certificates and accomplishments such as being an innovative knowledge-based company, evolved pharmaceutical company and also more than 17 Patent certificates throughout its years of activities.

Due to one of the prominent parts of our vision, doing our responsibilities for humanities and patients to be healed and cured with the newest choice of treatment, we are day by day being more eager to do our best with most up to date pharmaceutical knowledge by our great expert scientists. All these factors, as well as Parsian's standards and principles which is accompanied by high level of logistics and inventory management, its High-tech equipment contribute to a high degree of confidence from partners, leading to expand cooperation between Parsian pharmaceutical Co and leading Iranian pharmaceutical industries.

Sobhan Oncology
ACTOVERCO
ZISTDARU DANESH
KIMIA Pharmaceutical
Kharazmi
Aburaihan Pharmaceutical Co.
EXIR PHARMACEUTICAL CO.
abidi
Darou Pakhsh Pharmaceutical Mfg Co.

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Our **Produts:**

- Oncology
- Diabetes Mellitus
- Multiple Sclerosis
- Cardiovascular
- Central Nervous System
- Rheumatoid Arthritis
- Anemia

return

- Palbociclib
- letrozole
- Dasatinib
- Nilotinib
- Ibrutinib
- Imatinib
- Lenalidomide
- Erlotinib
- Gefitinib
- Crizotinib
- Osimertinib
- Vandetanib
- Pazopanib
- Sorafenib
- Regorafenib
- Sunitinib

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- Abemaclclib
- Abiraterone
- Dabrafenib
- Ixazomib
- Olaparib
- Ruxitinib
- Trametinib
- Venetoclax
- Lenvatinib

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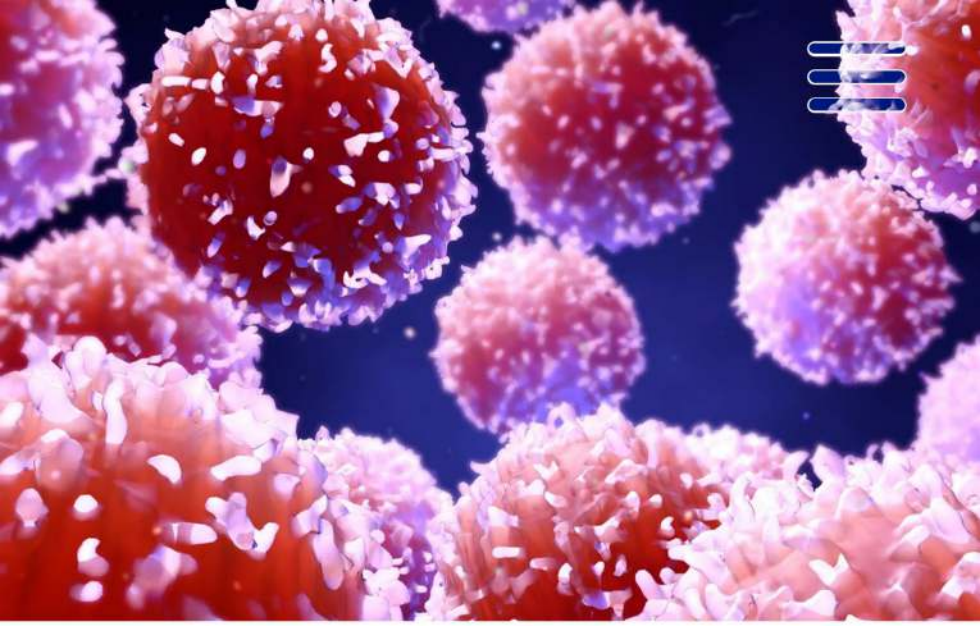
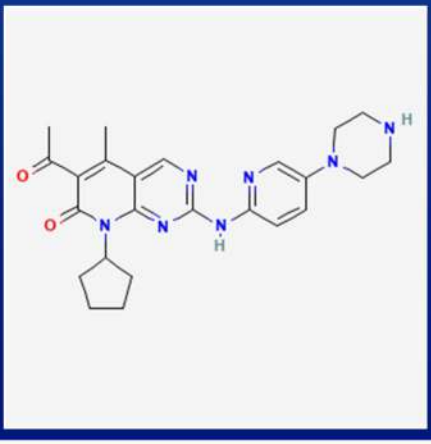


Due to the change that has been occurred in human's 21st century lifestyle, dealing with lots of daily stressors, obesity and many more life-threatening risk factors, one of the most leading cause of death and a dominant barrier to increase life expectancy in modern world is cancer. According to GLOBOCAN 2020, an estimated of 19.3 million new cancer cases (18.1 million excluding non-melanoma skin cancer) and nearly 10.0 million cancer deaths (9.9 million excluding non-melanoma skin cancer) has occurred, led cancer to ranks first or second main cause of death in nearly 112 or 183 countries and third or fourth in further 23 countries. On the basis of an estimation 1 in 3 people in the US are affected by cancer. According to the latest ranks and epidemiologic trends, cancer's rising prominence as a leading cause of death, which leads to cardiovascular disease ranks suppressed by cancer as a dominant cause of death.

Targeted therapies are now new class of interest for cancer due to the advantages including efficacy, selectivity and safety by acting on specific targets involved in proliferation and differentiation of cancer cells with minimal activity on normal cells compared with traditional oncologic ones. Small molecule inhibitors are one of the targeted cancer therapies, you can easily spot small molecule medicines because their generic name ends in "-IB." By December 2020, 89 small-molecule targeted antitumor medicines have been approved by the US FDA.

Palbociclib



Chemical information

IUPAC name
6-acetyl-8-cyclopentyl-5-methyl-2-[(5-piperazin-1-ylpyridin-2-yl)amino]pyrido[2,3-d]pyrimidin-7-one

CAS No.
571190-30-2

Molecular Weight
447.5 g·mol−1

Molecular Formula
C24H29N7O2

Granule Available
ready to fill ☑
ready to press ☐

Mechanism Of Action:

Palbociclib is a cyclin-dependent kinase 4/6 (CDK4/6) inhibitor that acts by binding to the ATP pocket with an IC50 in the range of 9-15 nmol/L. It is important to consider that it presents low to absent activity against other kinases.

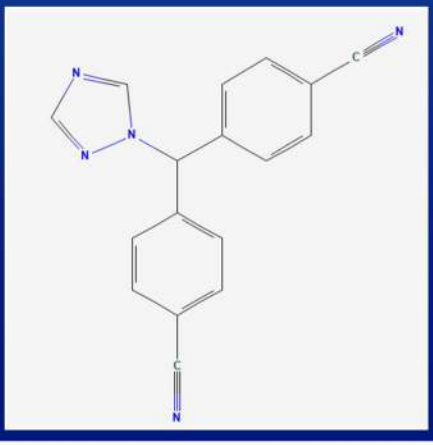
The CDK4/6 kinase is involved, with coregulatory partner cyclin D, in the G1-S transition. Hence, inhibition of this step prevents cell cycle progression in cells in whose this pathway is functioning. This step includes the pathways of the phosphorylation of retinoblastoma protein and the E2F family of transcription factors.

Indication:

Palbociclib is for hormone receptor positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (mBC)—breast cancer that has spread to other parts of the body—or HR+/HER2- mBC—can be used in men and women.

HR+, HER2- is the most common subtype of metastatic breast cancer, representing approximately 60% of all cases.

Letrozole



Chemical information

IUPAC name
4-[(4-cyanophenyl)-(1,2,4-triazol-1-yl)methyl]benzonitrile

CAS No.
112809-51-5

Molecular Weight
285.30 g·mol−1

Molecular Formula
C17H11N5

Mechanism Of Action:

Letrozole works by blocking the enzyme aromatase, which turns the hormone androgen into small amounts of estrogen in the body. This means less estrogen is available to stimulate the growth or hormone receptor-positive breast cancer cells.

Indication:

- **Adjuvant Treatment Of Early Breast Cancer**

Letrozole is indicated for the adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer.

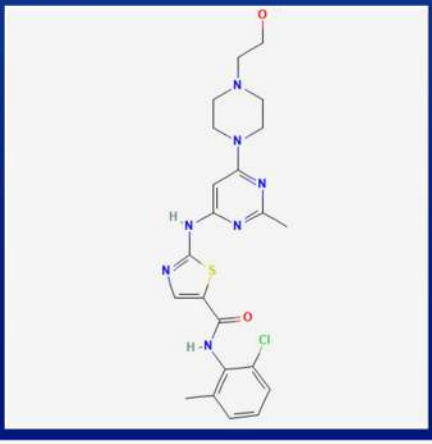
- **Extended Adjuvant Treatment Of Early Breast Cancer**

Letrozole is indicated for the extended adjuvant treatment of early breast cancer in postmenopausal women, who have received 5 years of adjuvant tamoxifen therapy.

- **First And Second-Line Treatment Of Advanced Breast Cancer**

Letrozole is indicated for first-line treatment of postmenopausal women with hormone receptor positive or unknown, locally advanced or metastatic breast cancer. Letrozole is also indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

Dasatinib Anhydrous



Chemical information

IUPAC name
N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)piperazin-1-yl]-2-methylpyrimidin-4-yl]amino]-1,3-thiazole-5-carboxamide

CAS No.
302962-49-8

Molecular Weight
488.0 g·mol−1

Molecular Formula
C22H26ClN7O2S

Mechanism Of Action:

Dasatinib, at nanomolar concentrations, inhibits the following kinases: BCR-ABL, SRC family (SRC, LCK, YES, FYN), c-KIT, EPHA2, and PDGFRβ. Based on modeling studies, dasatinib is predicted to bind to multiple conformations of the ABL kinase. In vitro, dasatinib was active in leukemic cell lines representing variants of imatinib mesylate sensitive and resistant disease. Dasatinib inhibited the growth of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) cell lines overexpressing BCR-ABL. Under the conditions of the assays, dasatinib was able to overcome imatinib resistance resulting from BCR-ABL kinase domain mutations, activation of alternate signaling pathways involving the SRC family kinases (LYN, HCK), and multi-drug resistance gene overexpression.

Indication:

• adults with newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.

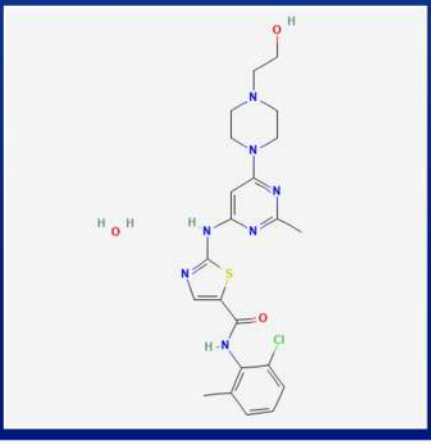
• adults with Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.

• adults with Ph+ acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment.

• children 1 year of age and older with Ph+ CML in chronic phase.

• children 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.

Dasatinib Monohydrate



Chemical information

IUPAC name
N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)piperazin-1-yl]-2-methylpyrimidin-4-yl]amino]-1,3-thiazole-5-carboxamide;hydrate

CAS No.
863127-77-9

Molecular Weight
506.0 g.mol−1

Molecular Formula
C22H28ClN7O3S

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

Dasatinib, at nanomolar concentrations, inhibits the following kinases: BCR-ABL, SRC family (SRC, LCK, YES, FYN), c-KIT, EPHA2, and PDGFRβ. Based on modeling studies, dasatinib is predicted to bind to multiple conformations of the ABL kinase. In vitro, dasatinib was active in leukemic cell lines representing variants of imatinib mesylate sensitive and resistant disease. Dasatinib inhibited the growth of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) cell lines overexpressing BCR-ABL. Under the conditions of the assays, dasatinib was able to overcome imatinib resistance resulting from BCR-ABL kinase domain mutations, activation of alternate signaling pathways involving the SRC family kinases (LYN, HCK), and multi-drug resistance gene overexpression.

Indication:

• adults with newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.

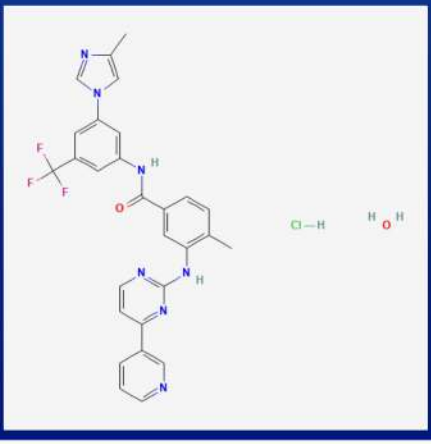
• adults with Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.

• adults with Ph+ acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment.

• children 1 year of age and older with Ph+ CML in chronic phase.

• children 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.

Nilotinib Hydrochloride Monohydrate



Chemical information

IUPAC name
4-methyl-N-[3-(4-methylimidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-ylpyrimidin-2-yl)amino]benzamide;hydrate;hydrochloride

CAS No.
923288-90-8

Molecular Weight
584.0 g.mol−1

Molecular Formula
C28H25ClF3N7O2

Granule Available
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ready to press ☐

Mechanism Of Action:

Chronic myelogenous leukemia (CML) is caused by the BCR-ABL oncogene. Nilotinib inhibits the tyrosine kinase activity of the BCR-ABL protein. Nilotinib fits into the ATP-binding site of the BCR-ABL protein with higher affinity than imatinib, over-riding resistance caused by mutations. The ability of Nilotinib to inhibit TEL-platelet-derived growth factor receptor-beta (TEL-PDGFRbeta), which causes chronic myelomonocytic leukemia, and FIP1-like-1-PDGFRalpha, which causes hyper eosinophilic syndrome, suggests potential use of Nilotinib for myeloproliferative diseases characterized by these kinase fusions. Nilotinib also inhibits the c-Kit receptor kinase, including the D816V-mutated variant of KIT, at pharmacologically achievable concentrations, supporting potential utility in the treatment of mastocytosis, and gastrointestinal stromal tumors.

Indication:

Nilotinib capsules is a prescription medicine used to treat:

- Adults with newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.

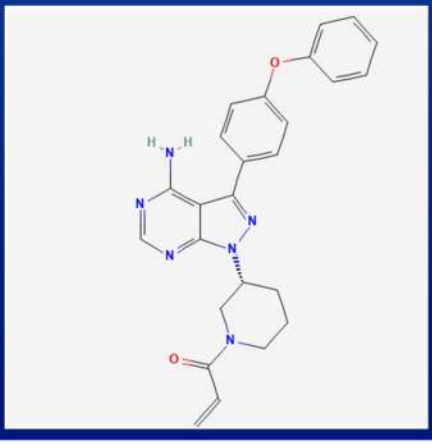
- Adults with Ph+ CML in chronic phase and accelerated phase who no longer benefit from, or did not tolerate, other treatment, including imatinib.

- Children (ages 1 year and older) with newly diagnosed Ph+ CML in chronic phase.

- Children (ages 1 year and older) with chronic phase Ph+ CML or accelerated phase Ph+ CML who:

- are no longer benefiting from treatment with a tyrosine kinase inhibitor medicine, or
- have taken another tyrosine kinase inhibitor medicine and cannot tolerate it.

Ibrutinib



Chemical information

IUPAC name
1-[(3R)-3-[4-amino-3-(4-phenoxyphenyl)pyrazolo[3,4-d]pyrimidin-1-yl]piperidin-1-yl]prop-2-en-1-one

CAS No.
936563-96-1

Molecular Weight
440.5 g·mol−1

Molecular Formula
C25H24N6O2

Granule Available
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Mechanism Of Action:

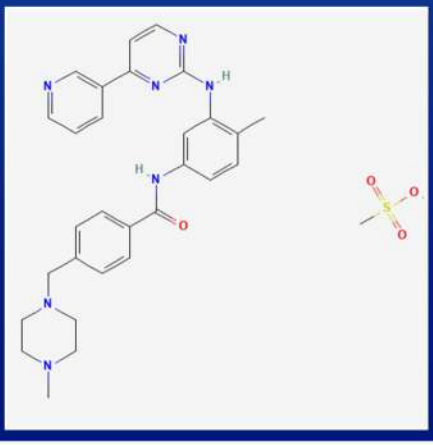
The B cell receptor (BCR) pathway regulates multiple cellular processes (such as proliferation, differentiation, and apoptosis) that are essential for the functioning and survival of both normal and malignant B cells.2 In B cell malignancies, such as CLL, aberrant BCR signaling plays a critical role in the pathogenesis of disease. The BCR pathway is responsible for the phosphorylation of numerous protein tyrosine kinases (PTKs), including Lyn, Syk, and Bruton's tyrosine kinase (Btk). These PTKs have been found to be constitutively active and over-expressed in CLL, leading to uncontrolled proliferation and survival of malignant B cells. Consequently, there has been rapid clinical development of inhibitors targeting these PTKs. Among the many PTKs involved in BCR signaling, Btk, a tyrosine kinase member of the Tec kinase family, is a distinctive therapeutic target. Upon BCR activation, Btk becomes activated by other PTKs, such as Lyn and Syk, resulting in activation of downstream transcription factors necessary for B cell proliferation and differentiation.

Ibrutinib is an orally administered, highly potent, selective, and irreversible small-molecule inhibitor of Btk. It forms a covalent bond with a cysteine residue (CYS-481) at the active site of Btk, leading to inhibition of Btk enzymatic activity. Ibrutinib also abrogates the full activation of Btk by inhibiting its auto phosphorylation at Tyr-223. This inhibition prevents downstream activation of the BCR pathway and subsequently blocks cell growth, proliferation, and survival of malignant B cells.

Indication:

- Mantle cell lymphoma (MCL) who have received at least one prior treatment
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion
- Waldenström's macroglobulinemia (WM)
- Marginal zone lymphoma (MZL) who require a medicine by mouth or injection (systemic therapy) and have received a certain type of prior treatment
- Chronic graft versus host disease (cGVHD) after failure of 1 or more lines of systemic therapy

Imatinib Mesylate



Chemical information

IUPAC name
Methanesulfonic acid; 4-[(4-methylpiperazin-1-yl) methyl] -N-[4-methyl-3-[(4-pyridin-3-ylpyrimidin-2-yl)amino]phenyl]benzamide

CAS No.
220127-57-1

Molecular Weight
589.7 g·mol−1

Molecular Formula
C30H35N7O4S

Granule Available
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ready to press ☑

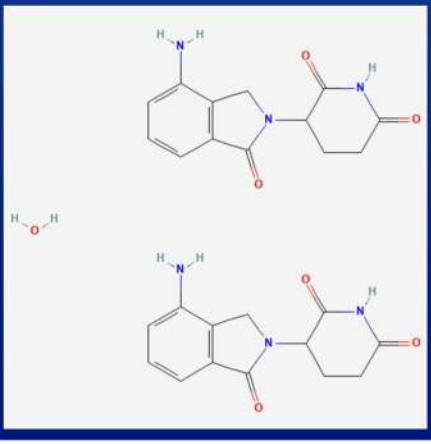
Mechanism Of Action:

Imatinib mesylate is a protein-tyrosine kinase inhibitor that inhibits the bcr-abl tyrosine kinase, the constitutive abnormal tyrosine kinase created by the Philadelphia chromosome abnormality in chronic myeloid leukemia (CML). It inhibits proliferation and induces apoptosis in bcr-abl positive cell lines as well as fresh leukemic cells from Philadelphia chromosome positive chronic myeloid leukemia.
Imatinib is also an inhibitor of the receptor tyrosine kinases for platelet-derived growth factor (PDGF) and stem cell factor (SCF), c-kit, and inhibits PDGF- and SCF-mediated cellular events. In vitro, imatinib inhibits proliferation and induces apoptosis in gastrointestinal stromal tumor (GIST) cells, which express an activating c-kit mutation.

Indication:

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase.
- Patients with Ph+ CML in blast crisis (BC), accelerated phase (AP), or in the chronic phase (CP) after failure of interferon-alpha therapy.
- Adult patients with relapsed or refractory Ph+ acute lymphoblastic leukemia (Ph+ ALL).
- Pediatric patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements.
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-KIT mutation or with c-KIT mutational status unknown.
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown.
- Adult patients with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP).
- Patients with KIT (CD117)-positive gastrointestinal stromal tumors (GIST) that cannot be surgically removed and/or have spread to other parts of the body.
- Adult patients after surgery who have had their KIT (CD117)-positive GIST completely removed.

Lenalidomide Hemihydrate



Chemical information

IUPAC name
3-(7-amino-3-oxo-1H-isoindol-2-yl)piperidine-2,6-di one;hydrate

CAS No.
847871-99-2

Molecular Weight
268.27 g·mol−1

Molecular Formula
C26H28N6O7

Granule Available
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ready to press ☐

Mechanism Of Action:

• Exhibits immunomodulatory properties.
  - Activates and increases number of T cells and NK cells
  - Increases number of NKT cells
  - Inhibits pro-inflammatory cytokines (e.g., TNF-a, and IL-6) by monocytes

• Inhibits cell proliferation and induces apoptosis of tumor cells in vitro and inhibition of tumor growth in vivo, leading to a decrease in tumor burden.

• Inhibits angiogenesis by reducing levels of VEGF, TNF-a, and IL-6.

Indication:

• Newly diagnosed multiple myeloma in patients who have undergone autologous stem cell transplantation

• Newly diagnosed multiple myeloma in patients not eligible for transplant,Multiple myeloma in patients who have received at least one prior therapy

• Myelodysplastic syndromes

• Mantle cell lymphoma

• Follicular lymphoma

Erlotinib Hydrochloride

Chemical information

IUPAC name
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine;hydrochloride

CAS No.
183319-69-9

Molecular Weight
429.9 g·mol−1

Molecular Formula
C22H24ClN3O4

Granule Available
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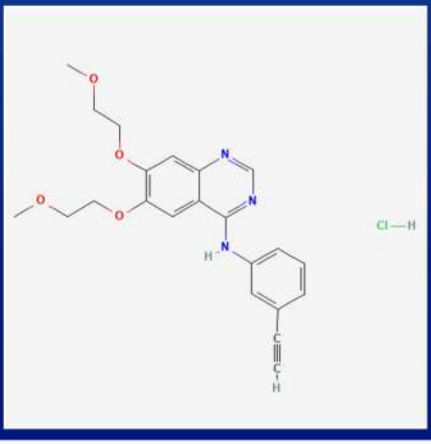


Mechanism Of Action:

Erlotinib, belongs to the group 'EGFR inhibitors'. Erlotinib blocks EGFRs, which can be found on some tumor cells. As a result of this block, the tumor cells can no longer receive the messages needed for growing and for spreading (metastasis). As a result, Erlotinib helps to stop the cancer from growing and spreading through the body.

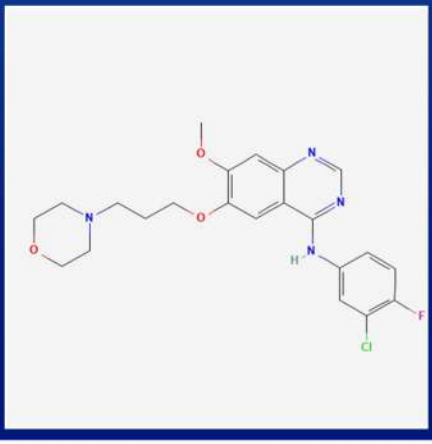
Indication:

1. Erlotinib is a cancer medicine used in non small-cell lung cancer (NSCLC) that is advanced or metastatic. It is used for:

• previously untreated patients whose cancer cells have certain changes ('activating mutations') in the gene for a protein called epidermal growth factor receptor (EGFR);
• Patients with EGFR activating mutations whose disease is stable after initial chemotherapy. Stable means that the cancer has neither improved nor worsened with chemotherapy (medicines to treat cancer);
• patients with EGFR activating mutations in whom previous chemotherapy has not worked;
• Patients without EGFR activating mutations in whom previous chemotherapy has not worked and other treatments are unsuitable.

2. Erlotinib is also used in patients with metastatic pancreatic cancer

Gefitinib



Chemical information

IUPAC name
N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine

CAS No.
184475-35-2

Molecular Weight
446.9 g·mol−1

Molecular Formula
C22H24ClFN4O3

Granule Available
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ready to press ☑

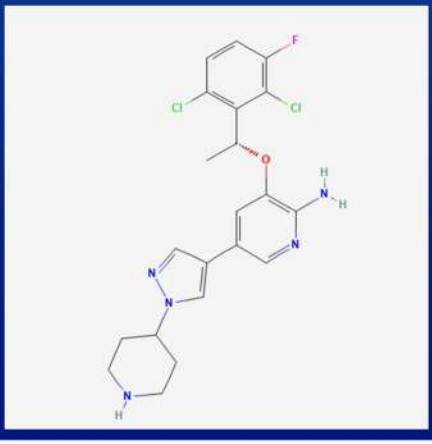
Mechanism Of Action:

Gefitinib is an inhibitor of the epidermal growth factor receptor (EGFR) tyrosine kinase that binds to the adenosine triphosphate (ATP)-binding site of the enzyme. EGFR is often shown to be overexpressed in certain human carcinoma cells, such as lung and breast cancer cells. Overexpression leads to enhanced activation of the anti-apoptotic Ras signal transduction cascades, subsequently resulting in increased survival of cancer cells and uncontrolled cell proliferation. Gefitinib is the first selective inhibitor of the EGFR tyrosine kinase. By inhibiting EGFR tyrosine kinase, the downstream signaling cascades are also inhibited, resulting in inhibited malignant cell proliferation.

Indication:

Gefitinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. □

Crizotinib



Chemical information

IUPAC name
3-[(1R)-1-(2,6-dichloro-3-fluorophenyl)ethoxy]-5-(1-piperidin-4-ylpyrazol-4-yl)pyridin-2-amine

CAS No.
877399-52-5

Molecular Weight
450.3 g·mol−1

Molecular Formula
C21H22Cl2FN5O

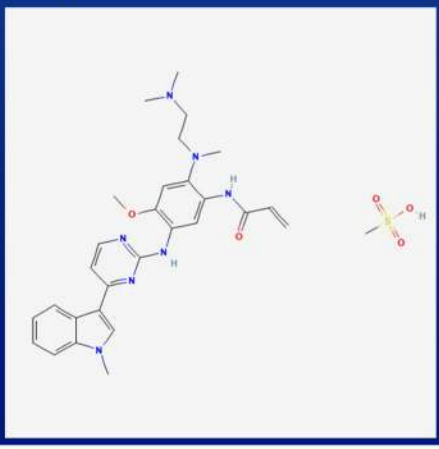
Mechanism Of Action:

Crizotinib is a tyrosine kinase receptor inhibitor. More specifically, it inhibits anaplastic lymphoma kinase (ALK), hepatocyte growth factor receptor (HGFR, c-MET), and Recepteur d'Origine Nantais (RON). Abnormalities in the ALK gene caused by mutations or translocations may lead to expression of oncogenic fusion proteins. In patients with NSCLC, they have the EML4-ALK gene. Crizotinib inhibits ALK tyrosine kinase which ultimately results in decreased proliferation of cells that carry the genetic mutation and tumor survivability.

Indication:

Crizotinib is a prescription medicine used to treat people with non-small cell lung cancer (NSCLC) that has spread to other parts of the body and is caused by a defect in either a gene called ALK (anaplastic lymphoma kinase) or a gene called ROS1.

Osimertinib Mesylate



Chemical information

IUPAC name
N-[2-[2-(dimethylamino)ethyl-methylamino]-4-methoxy-5-[[4-(1-methylindol-3-yl)pyrimidin-2-yl]amino]phenyl]prop-2-enamide;methanesulfonic acid

CAS No.
1421373-66-1

Molecular Weight
595.7 g·mol−1

Molecular Formula
C29H37N7O5S

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

Osimertinib is an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) that binds to certain mutant forms of EGFR (T790M, L858R, and exon 19 deletion) that predominate in non-small cell lung cancer (NSCLC) tumors following treatment with first-line EGFR-TKIs. As a third-generation tyrosine kinase inhibitor, osimertinib is specific for the gate-keeper T790M mutation which increases ATP binding activity to EGFR and results in poor prognosis for late-stage disease. Furthermore, osimertinib has been shown to spare wild-type EGFR during therapy, thereby reducing non-specific binding and limiting toxicity.

Indication:

• Osimertinib is indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

• Osimertinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

• Osimertinib is indicated for the treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy

Vandetanib

Chemical information

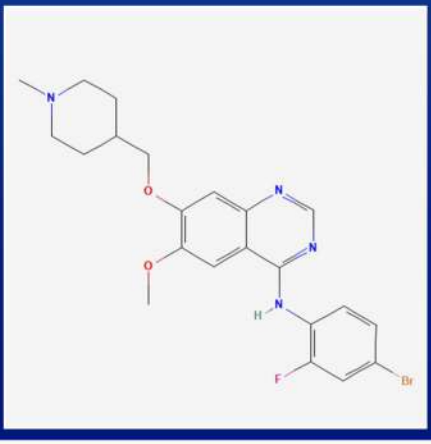
IUPAC name
N-(4-bromo-2-fluorophenyl)-6-methoxy-7-[(1-methyl piperidin-4-yl)methoxy]quinazolin-4-amine

CAS No.
443913-73-3

Molecular Weight
475.4 g·mol−1

Molecular Formula
C22H24BrFN4O2

Granule Available
ready to fill ☐
ready to press ☑



Mechanism Of Action:

Vandetanib is a potent and selective inhibitor of VEGFR (vascular endothelial growth factor receptor), EGFR (epidermal growth factor receptor) and RET (RE-arranged during Transfection) tyrosine kinases.

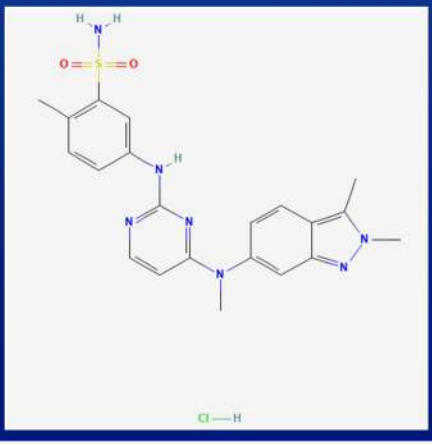
VEGFR- and EGFR-dependent signaling are both clinically validated pathways in cancer, including non-small-cell lung cancer (NSCLC). RET activity is important in some types of thyroid cancer, and early data with vandetanib in medullary thyroid cancer has led to orphan-drug designation by the regulatory authorities in the USA and EU.

Indication:

Vandetanib is a kinase inhibitor indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

*Use vandetanib in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of vandetanib.

Pazopanib Hydrochloride



Chemical information

IUPAC name
5-[[4-[(2,3-dimethylindazol-6-yl)-methylamino]pyrimidin-2-yl]amino]-2-methylbenzenesulfonamide;hydrochloride

CAS No.
635702-64-6

Molecular Weight
474.0 g·mol−1

Molecular Formula
C21H24ClN7O2S

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

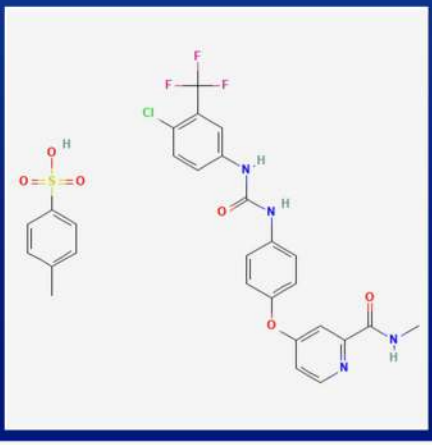
Pazopanib is a second-generation multi-targeted tyrosine kinase inhibitor against vascular endothelial growth factor receptor-1, -2, and -3, platelet-derived growth factor receptor-alpha, platelet-derived growth factor receptor-beta, and c-kit. These receptor targets are part of the angiogenesis pathway that facilitates the formation of tumor blood vessel for tumor survival and growth.

Indication:

• First-line treatment of advanced renal cell carcinoma, Treatment of advanced renal cell carcinoma in patients who have had previous treatment with cytokine therapy.

• Treatment of adult patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy.

Sorafenib Tosylate



Chemical information

IUPAC name
4-[4-[[4-chloro-3-(trifluoromethyl)phenyl]carbamoylamino]phenoxy]-N-methylpyridine-2-carboxamide;4-methylbenzenesulfonic acid

CAS No.
475207-59-1

Molecular Weight
637.0 g·mol−1

Molecular Formula
C28H24ClF3N4O6S

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

• Decreased tumor cell proliferation has been demonstrated in vitro.

• Sorafenib was shown to inhibit multiple intracellular (c-CRAF, BRAF, and mutant BRAF) and cell surface kinases (KIT, FLT-3, RET, RET/PTC, VEGFR-1, VEGFR-2, VEGFR-3, and PDGFR–ß).

• Several of these kinases are thought to be involved in tumor cell signaling, angiogenesis, and apoptosis.

• Sorafenib inhibited tumor growth and increased tumor apoptosis in models of hepatocellular carcinoma (HCC), renal cell carcinoma (RCC), and differentiated thyroid cancer (DTC).

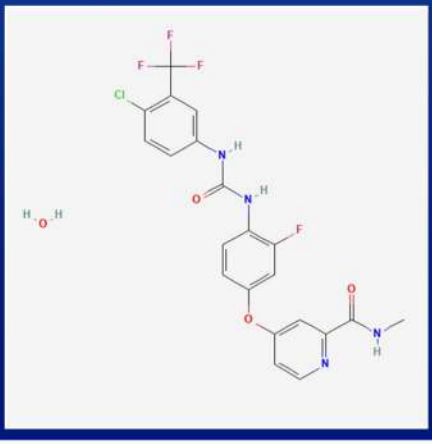
Indication:

• The treatment of patients with unresectable hepatocellular carcinoma (HCC).

• The treatment of patients with advanced renal cell carcinoma (RCC).

• The treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

Regorafenib Monohydrate



Chemical information

IUPAC name
4-[4-[[4-chloro-3-(trifluoromethyl)phenyl]carbamoylamino]-3-fluoroph enoxy]-N-methylpyridine-2-carboxamide;hydrate

CAS No.
1019206-88-2

Molecular Weight
500.8 g·mol−1

Molecular Formula
C21H17ClF4N4O4

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

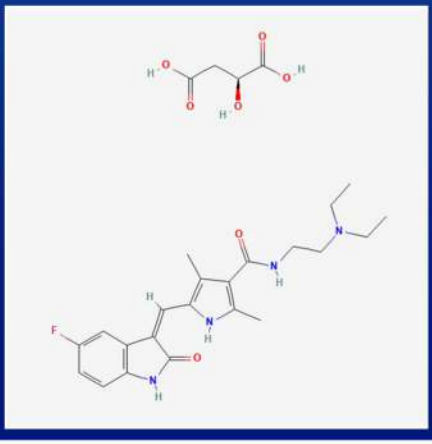
Regorafenib is a small molecule inhibitor of multiple membrane-bound and intracellular kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment. In in vitro biochemical or cellular assays, regorafenib or its major human active metabolites M-2 and M-5 inhibited the activity of RET, VEGFR1, VEGFR2, VEGFR3, KIT, PDGFR-alpha, PDGFR-beta, FGFR1, FGFR2, TIE2, DDR2, TrkA, Eph2A, RAF-1, BRAF, BRAFV600E , SAPK2, PTK5, and Abl at concentrations of regorafenib that have been achieved clinically. In in vivo models, regorafenib demonstrated anti-angiogenic activity in a rat tumor model, and inhibition of tumor growth as well as anti-metastatic activity in several mouse xenograft models including some for human colorectal carcinoma.

Indication:

Regorafenib is a once-daily, oral prescription anticancer medicine, indicated for:

- The treatment of colon or rectal cancer that has spread to other parts of the body and for which they have received previous treatment with certain chemotherapy medicines.
- The treatment of a rare stomach, bowel, or esophagus cancer called GIST (gastrointestinal stromal tumor) that cannot be treated with surgery or that has spread to other parts of the body and for which they have received previous treatment with certain medicines.
- The treatment of a type of liver cancer called hepatocellular carcinoma (HCC) in people who have been previously treated with sorafenib.

Sunitinib Malate



Chemical information

IUPAC name
N-[2-(diethylamino)ethyl]-5-[(Z)-(5-fluoro-2-oxo-1H-indol-3-ylidene) methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide;(2S)-2-hydroxybutanedioic acid

CAS No.
341031-54-7

Molecular Weight
532.6 g·mol−1

Molecular Formula
C26H33FN4O7

Granule Available
ready to fill ☑
ready to press ☐

Mechanism Of Action:

Sunitinib is a small molecule that inhibits multiple receptor tyrosine kinases (RTKs), some of which are implicated in tumor growth, pathologic angiogenesis, and metastatic progression of cancer. Sunitinib was evaluated for its inhibitory activity against a variety of kinases (>80 kinases) and was identified as an inhibitor of platelet-derived growth factor receptors (PDGFRa and PDGFRb), vascular endothelial growth factor receptors (VEGFR1, VEGFR2 and VEGFR3), stem cell factor receptor (KIT), Fms-like tyrosine kinase-3 (FLT3), colony stimulating factor receptor Type 1 (CSF-1R), and the glial cell-line derived neurotrophic factor receptor (RET).

Indication:

- Sunitinib is used to treat advanced kidney cancer (advanced renal cell carcinoma or RCC).
- Sunitinib is used to treat a rare cancer of the stomach, bowel, or esophagus called gastrointestinal stromal tumor (GIST) and when you have taken the medicine imatinib mesylate and it did not stop the cancer from growing or you cannot take imatinib mesylate.
- Sunitinib is used to treat a type of pancreatic cancer known as pancreatic neuroendocrine tumors (pNET) that has progressed and cannot be treated with surgery.
- Sunitinib is used to treat adults with kidney cancer that has not spread and who are at high risk of RCC coming back again after having kidney surgery.

ABEMACICLIB

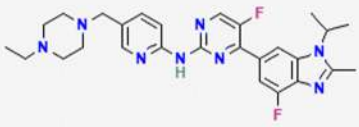
Chemical information

IUPAC name
N-{3-{3-Cyclopropyl-5-[(2-fluoro-4-iodophenyl)amino]-6,8-dimethyl-2,4,7-trioxo-3,4,6,7-tetrahydropyrido[4,3-d]pyrimidin-1(2H)-yl}phenyl}acetamide

CAS No.
1231929-97-7

Molecular Weight
506.59g/mol

Molecular Formula
C27H32F2N8



Mechanism Of Action:

Abemaciclib demonstrates high selectivity in inhibiting CDK4 and CDK6 with potent activity in the low nanomolar range. By inhibiting the phosphorylation of Rb, it induces a G1 cell cycle arrest and effectively hinders cell proliferation. Importantly, abemaciclib's activity is specifically targeted towards Rb-proficient cells.

Indication:

- Breast Cancer

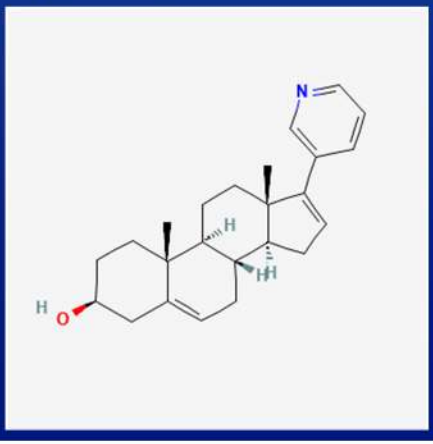
When used alongside an aromatase inhibitor or tamoxifen, abemaciclib is indicated for adjuvant treatment in adults with hormone receptor-positive, human epidermal growth factor receptor type 2 (HER2)-negative, node-positive, early-stage breast cancer. This therapy is specifically recommended for individuals at high risk of recurrence, whose Ki-67 score (determined by an FDA-approved test) is equal to or exceeds 20%.

For the initial treatment of hormone receptor-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women and men, abemaciclib is administered in combination with an aromatase inhibitor such as anastrozole or letrozole.

Abemaciclib, in combination with fulvestrant, is utilized for the treatment of hormone receptor-positive, HER2-negative advanced or metastatic breast cancer in adults who have experienced disease progression following prior endocrine therapy.

Abemaciclib is employed as a monotherapy for the treatment of hormone receptor-positive, HER2-negative advanced or metastatic breast cancer in adults who have undergone disease progression following endocrine therapy and prior chemotherapy for metastatic disease.

ABIRATERONE ACETATE



Chemical information

IUPAC name
[(3S,8R,9S,10R,13S,14S)-10,13-dimethyl-17-pyridin-3-yl-2,3,4,7,8,9,11,12,14,15-decahydro-1H-cyclopenta[a]phenanthren-3-yl] acetate

CAS No.
154229-18-2

Molecular Weight
349.509 g/mol

Molecular Formula
C24H31NO

Mechanism Of Action:

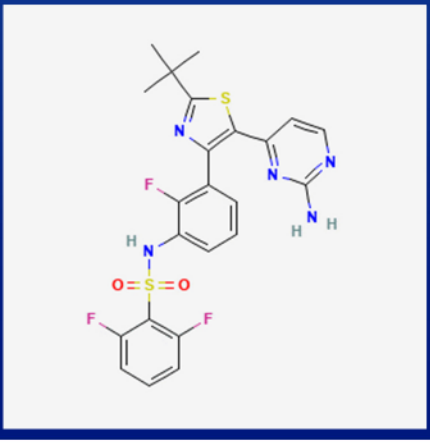
Abiraterone is an orally active inhibitor of the steroidal enzyme CYP17A1, also known as 17 alpha-hydroxylase/C17,20 lyase. It exerts its inhibitory effects on CYP17A1 in a selective and irreversible manner through covalent binding. CYP17A1 plays a crucial role in the biosynthesis of androgens and is highly expressed in testicular, adrenal, and prostatic tumor tissue. Specifically, abiraterone targets the conversion of 17-hydroxyprogesterone to dehydroepiandrosterone (DHEA) by inhibiting the enzymatic activity of CYP17A1. This leads to a reduction in serum levels of testosterone and other androgens

Indication:

- Prostate Cancer

It is used in combination with prednisone for the treatment of metastatic castration-resistant prostate cancer. Micronized abiraterone, on the other hand, is combined with methylprednisolone for the treatment of the same condition. The efficacy of micronized abiraterone is determined based on studies evaluating the effects of conventional abiraterone. Additionally, conventional abiraterone, when combined with prednisone, is employed for the treatment of high-risk metastatic castration-sensitive prostate cancer. Treatment guidelines recommend combining androgen deprivation therapy with abiraterone, apalutamide, enzalutamide, or docetaxel for the management of metastatic noncastrate (hormone-sensitive) prostate cancer

DABRAFENIB MESYLATE



Chemical information

IUPAC name
N-{3-[5-(2-aminopyrimidin-4-yl)-2-tert-butyl-1,3-thiazol-4-yl]-2-fluorophenyl}-2,6-difluorobenzenesulfonamide

CAS No.
1195768-06-9

Molecular Weight
519.56 g/mol

Molecular Formula
C23H20F3N5O2S2

Mechanism Of Action:

Dabrafenib is recognized as a competitive and highly selective inhibitor of BRAF. Its mechanism of action involves binding to the ATP pocket of BRAF. While dabrafenib has the ability to inhibit wild-type BRAF, it exhibits a notably stronger affinity towards mutant variants of BRAF such as BRAF V600E, BRAF V600K, and BRAF V600D

Indication:

- Melanoma

in combination with trametinib, is employed as an adjuvant therapy subsequent to the complete resection of melanoma that involves nodal involvement and carries either the BRAF V600E or V600K mutation.

- NSCLC

in conjunction with trametinib, is prescribed for the management of metastatic non-small cell lung cancer (NSCLC) in patients presenting the BRAF V600E mutation. This specific utilization has been granted orphan drug

- Anaplastic Thyroid Cancer

Dabrafenib, when combined with trametinib, is employed as a therapeutic approach for locally advanced or metastatic anaplastic thyroid cancer in patients with the BRAF V600E mutation, especially in cases where satisfactory locoregional treatment options are not viable. The FDA has recognized and designated this particular drug combination as an orphan drug for the treatment of anaplastic thyroid cancer with the BRAF V600E mutation.

IXAZOMIB CITRATE

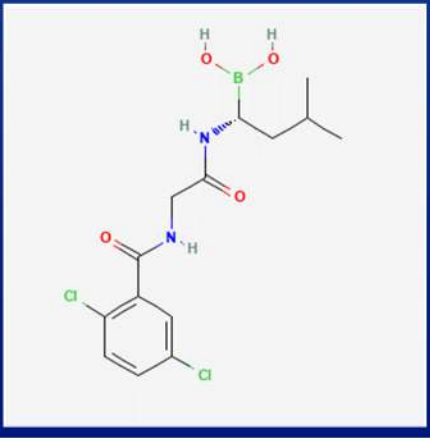
Chemical information

IUPAC name
N2-(2,5-Dichlorobenzoyl)-N-[(1R)-1-(dihydroxyboryl)-3-methylbutyl]glycinamide

CAS No.
1239908-20-3

Molecular Weight
361.03 g/mol

Molecular Formula
C24H31NO



Mechanism Of Action:

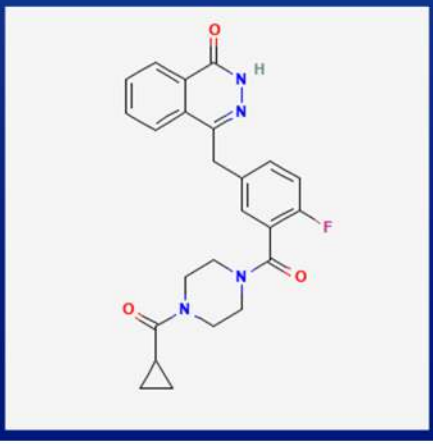
Ixazomib functions by obstructing protein degradation through the inhibition of the 20S catalytic subunit of the 26S proteasome. Specifically, at lower concentrations, MLN2238 targets and inhibits the β5 chymotrypsin-like subunit, which is responsible for cleaving proteins after hydrophobic residues. This mechanism effectively hinders the proteasome's ability to degrade proteins

Indication:

•Multiple Myeloma

Ixazomib is used in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma that has been previously treated with at least one prior therapy. This combination therapy has been designated as an orphan drug for this specific use.

OLAPARIB



Chemical information

IUPAC name
4-[(3-[(4-cyclopropylcarbonyl)piperazin-1-yl]carbonyl) -4-fluorophe-nyl]methyl(2H)phthalazin-1-one

CAS No.
763113-22-0

Molecular Weight
435.08 g/mol

Molecular Formula
C24H23FN4O3

Mechanism Of Action:

Olaparib functions as an inhibitor of poly(ADP-ribose) polymerase, effectively impeding the repair of single-strand DNA breaks. This mechanism leads to synthetic lethality in BRCA-associated cancer cells, characterized by a malfunction in the homologous recombination DNA repair pathway.

Indication:

•Ovarian Cancer

Olaparib is utilized as a standalone treatment for maintaining adults with confirmed or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. This maintenance therapy is specifically intended for patients who have achieved a complete or partial response to first-line platinum-based chemotherapy. The FDA has designated olaparib as an orphan drug for this precise indication. It is crucial to perform an FDA-approved companion diagnostic test before initiating therapy to confirm the presence of specific biomarkers.

•Breast Cancer

This specific indication applies to patients who have received prior chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. For patients with hormone receptor-positive breast cancer, prior treatment with endocrine therapy is necessary unless clinically contraindicated. Prior to initiating therapy, the presence of specific biomarkers must be confirmed using an FDA-approved companion diagnostic test.

•Prostate Cancer

Olaparib is used as a monotherapy for the treatment of adults with confirmed or suspected deleterious germline or somatic mutations in homologous recombination repair (HRR) genes, who are diagnosed with metastatic castration-resistant prostate cancer and have experienced progression after prior treatment with enzalutamide or abiraterone. Prior to initiating therapy, the presence of specific biomarkers must be confirmed using an FDA-approved companion diagnostic test.

RUXOLITINIB PHOSPHATE

Chemical information

IUPAC name
(3R)-3-Cyclopentyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)pyrazol-1-yl]propanenitrile

CAS No.
1092939-17-7

Molecular Weight
306.37 g/mol

Molecular Formula
C17H18N6

Mechanism Of Action:

Ruxolitinib belongs to the drug class called janus kinase inhibitors (JAK inhibitors). It acts as an inhibitor of the JAK1 and JAK2 protein kinases and functions by competitively inhibiting the ATP-binding catalytic site on both JAK1 and JAK2. This mechanism of action allows ruxolitinib to effectively hinder the activity of these protein kinase

Indication:

•Polycythemia Vera

Ruxolitinib is indicated for the treatment of polycythemia vera in adults who have a history of inadequate response to or intolerance to hydroxyurea. The FDA has designated it as an orphan drug for this specific therapeutic application.

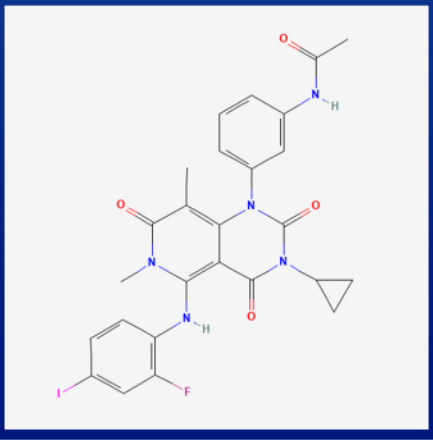
•Acute Graft-Versus-Host Disease

Ruxolitinib is prescribed for the treatment of acute graft-versus-host disease (GVHD) in adults and pediatric patients aged 12 years and above, specifically for cases that do not respond to corticosteroid treatment. This particular use of ruxolitinib has been granted orphan drug designation by the FDA

•Chronic Graft-Versus-Host Disease

Some experts suggest that ruxolitinib can be considered as a second-line therapy option for patients with chronic GVHD who are already receiving corticosteroids. This recommendation applies to both adults and pediatric patients aged 12 years and older who have previously failed 1 or 2 systemic therapy regimens. It is important to note that the FDA has designated ruxolitinib as an orphan drug for the treatment of chronic GVHD, recognizing its potential benefits in this specific condition.

TRAMETINIB DIMETHYL SULFOXIDE



Chemical information

IUPAC name
N-(3-{3-Cyclopropyl-5-[(2-fluoro-4-iodophenyl)amino]-6,8-dimethyl-2,4,7-trioxo-3,4,6,7-tetrahydropyrido[4,3-d]pyrimidin-1(2H)-yl}phenyl)acetamide

CAS No.
1187431-43-1

Molecular Weight
615.39g/mol

Molecular Formula
C26H23FIN5O4

Mechanism Of Action:

Trametinib is identified as a reversible and remarkably selective allosteric inhibitor of MEK1 and MEK2. Through its high-affinity binding to unphosphorylated MEK1 and MEK2, trametinib effectively impedes the catalytic activity of these enzymes. Moreover, it plays a crucial role in preserving MEK in an unphosphorylated state, consequently impeding the phosphorylation and subsequent activation of MEKs.

Indication:

•Melanoma

In the context of adjuvant therapy, trametinib is utilized in combination with dabrafenib following the complete surgical removal of melanoma that involves nodal involvement and carries either the BRAF V600E or V600K mutation

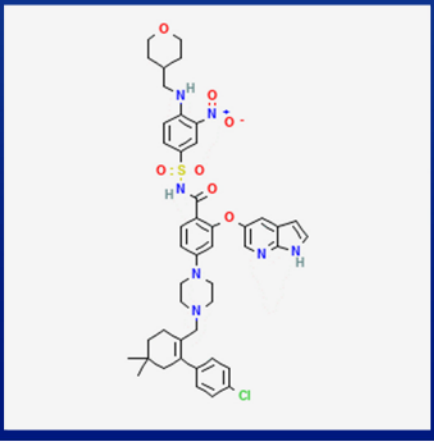
•NSCLC

Trametinib, when combined with dabrafenib, is employed as a treatment strategy for metastatic non-small cell lung cancer (NSCLC) in patients with the BRAF V600E mutation. This specific combination has been designated as an orphan drug by the FDA for this particular application.

•Anaplastic Thyroid Cancer

Trametinib, in conjunction with dabrafenib, is utilized as a treatment approach for locally advanced or metastatic anaplastic thyroid cancer in patients with the BRAF V600E mutation when other satisfactory locoregional treatment options are not available. The FDA has designated this particular combination as an orphan drug for this specific therapeutic application.

VENETOCLAX



Chemical information

IUPAC name
4-(4-{[2-(4-Chlorophenyl)-4,4-dimethyl-1-cyclohexen-1-yl]methyl}-1-piperazinyl)-N-({3-nitro-4-[(tetrahydro-2H-pyran-4-ylmethyl)amino]phenyl}sulfonyl)-2-(1H-pyrrolo[2,3-b]pyridin-5-yloxy)benzamide

CAS No.
1257044-40-8

Molecular Weight
868.44 g/mol

Molecular Formula
C45H50ClN7O7S

Mechanism Of Action:

Venetoclax, as the first and only BCL-2 inhibitor, plays a crucial role in restoring the apoptotic process in newly diagnosed acute myeloid leukemia (AML). The suppression of the apoptotic pathway is a critical mechanism for the survival and proliferation of hematologic cancer cells. These findings are supported by preclinical studies.

Indication:

- **Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)**

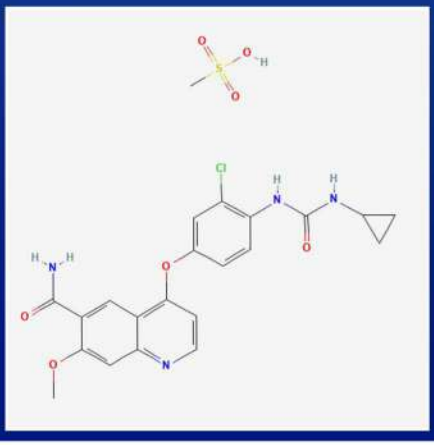
Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are similar diseases that primarily affect lymphocytes, a type of white blood cell. The treatment approach for CLL and SLL can be similar, and there are several options available depending on the stage and characteristics of the disease.

- One notable treatment option that has been designated an orphan drug by the U.S. Food and Drug Administration (FDA) for the treatment of CLL/SLL is ibrutinib (Imbruvica). Ibrutinib is a targeted therapy that inhibits a protein called Bruton's tyrosine kinase (BTK), which is involved in the survival and proliferation of CLL and SLL cells. It is generally recommended among the first-line treatment options for symptomatic CLL.

Acute Myeloid Leukemia (AML)

Venetoclax, in combination with azacitidine, decitabine, or low-dose cytarabine, is employed as a treatment for newly diagnosed acute myeloid leukemia (AML) in patients who are 75 years of age or older or have comorbidities that make them unsuitable for intensive induction chemotherapy. This therapeutic approach is specifically recommended to address the needs of these patient populations

Lenvatinib Mesylate



Chemical information

IUPAC name
4-[3-chloro-4-(cyclopropylcarbamoylamino)phenoxy]-7-methoxy quinoline-6-carboxamide;methanesulfonic acid

CAS No.
857890-39-2

Molecular Weight
523.0 g·mol−1

Molecular Formula
C22H23ClN4O7S

Mechanism Of Action:

Lenvatinib is a receptor tyrosine kinase (RTK) inhibitor that inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors VEGFR1 (FLT1), VEGFR2 (KDR), and VEGFR3 (FLT4). Lenvatinib also inhibits other RTKs that have been implicated in pathogenic angiogenesis, tumor growth, and cancer progression in addition to their normal cellular functions, including fibroblast growth factor (FGF) receptors FGFR1, 2, 3, and 4; the platelet derived growth factor receptor alpha (PDGFRα), KIT, and RET.

Indication:

- Differentiated Thyroid Cancer (DTC)

•For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory DTC.

- Renal Cell Carcinoma (RCC)

• For the first-line treatment of adult patients with advanced RCC.
• For the treatment of adult patients with advanced RCC following one prior anti-angiogenic therapy.

- Hepatocellular Carcinoma (HCC)

• For the first-line treatment of patients with unresectable HCC.

- Endometrial Carcinoma (EC)

• For the treatment of patients with advanced EC, that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy, and are not candidates for curative surgery or radiation.

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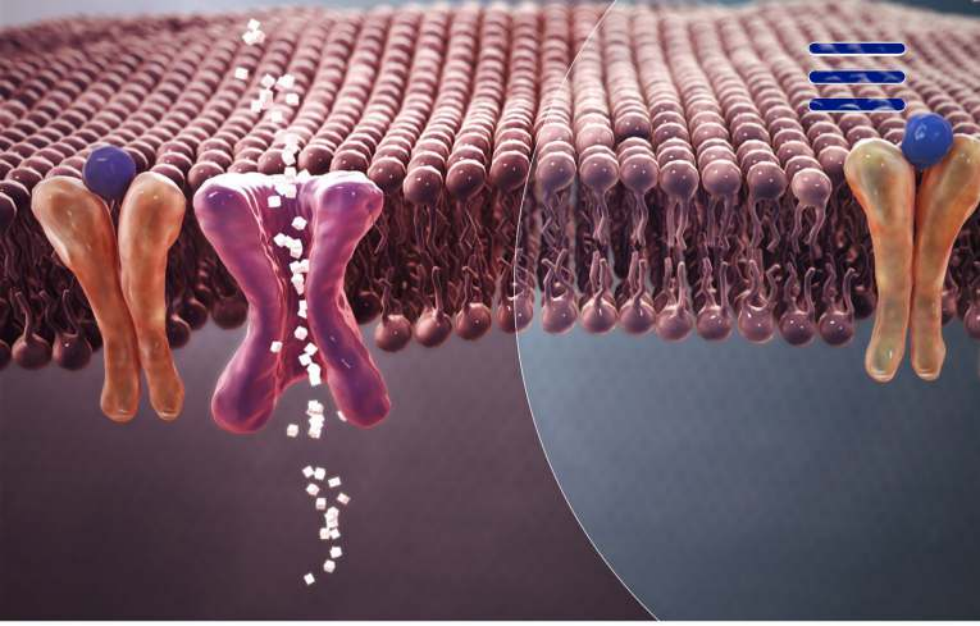
Empagliflozin

Linagliptin

Dapagliflozin

Sitagliptin

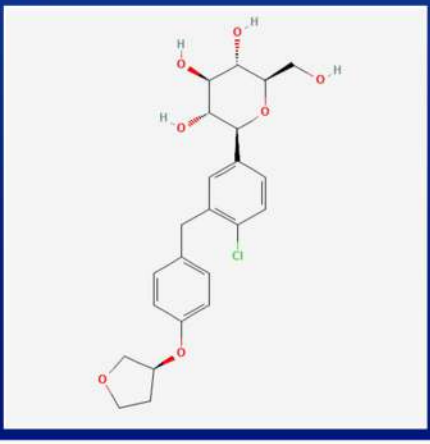
Parsian pharmaceutical co



Diabetes is a chronic, metabolic disease that affects how your body turns food into energy, in which carbohydrate, protein, and fat metabolism is impaired. This metabolic health disorder characterized by elevated levels of blood glucose due to unstable insulin secretion, insulin resistance secretion, or both; in long-term leads to severe damage to the heart, blood vessels, nerves, eyes and kidneys. The most common type especially in adults is a diabetes mellitus type2, which occurs when the body doesn't make enough insulin or becomes resistant to insulin. The prevalence of type 2 diabetes has risen remarkably in countries of all income levels in the last decades. Type 1 diabetes which formerly known as insulin-dependent diabetes or juvenile diabetes is a long-term health problem in which little or no insulin is produced by pancreas.

There is something about 422 million diabetic patients worldwide, most of them living in low-and middle-income countries, and leads to 1.5million deaths each year. The most considerable point is that in the last decades the number of diabetic patients and the prevalence of diabetes have been steadily increasing. According to prevalence incidence of diabetes in adults aged 18 years and older in 2014 which was around 8.5 percent globally, numerous estimates predict that the number of diabetic patients globally will be risen from 422 million to 642 million by 2040. The highest prevalence of diabetes compared to other WHO regions was belonged to the Eastern Mediterranean Region (EMRO), which was 13.7% in 2014.

Empagliflozin



Chemical information

IUPAC name
(2S,3R,4R,5S,6R)-2-[4-chloro-3-[[4-[(3S)-oxolan-3-yl]oxyphenyl]methyl]phenyl]-6-(hydroxymethyl)oxane-3,4,5-triol

CAS No.
864070-44-0

Molecular Weight
450.9 g·mol−1

Molecular Formula
C23H27ClO7

Mechanism Of Action:

The vast majority of glucose filtered through the glomerulus is reabsorbed within the proximal tubule, primarily via SGLT2 (sodium-glucose linked co-transporter-2) which is responsible for ~90% of the total glucose reabsorption within the kidneys. Empagliflozin is a potent inhibitor of renal SGLT2 transporters located in the proximal tubules of the kidneys and works to lower blood glucose levels via an increase in glycosuria.

Empagliflozin also appears to exert cardiovascular benefits - specifically in the prevention of heart failure - independent of its blood glucose-lowering effects, though the exact mechanism of this benefit is not precisely understood. Several theories have been posited, including the potential inhibition of Na+/H+ exchanger (NHE) 1 in the myocardium and NHE3 in the proximal tubule, reduction of pre-load via diuretic/natriuretic effects and reduction of blood pressure, prevention of cardiac fibrosis via suppression of

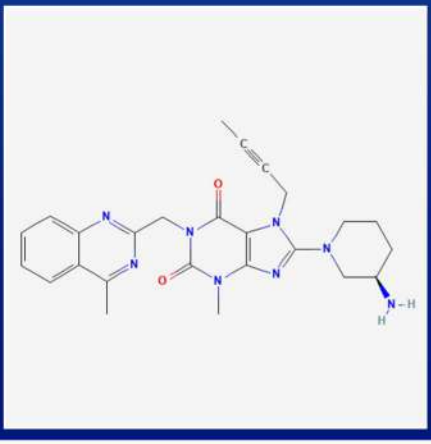
Indication:

• As a helping agent for improving glycemic control in adult patients with type 2 diabetes mellitus.

• For reducing the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

• For reducing the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced or preserved ejection fraction.(HF-rEF or HF-pEF)

Linagliptin



Chemical information

IUPAC name
8-[(3R)-3-aminopiperidin-1-yl]-7-but-2-ynyl-3-methyl-1-[(4-methylquinazolin-2-yl)methyl]purine-2,6-dione

CAS No.
668270-12-0

Molecular Weight
472.5 g·mol−1

Molecular Formula
C25H28N8O2

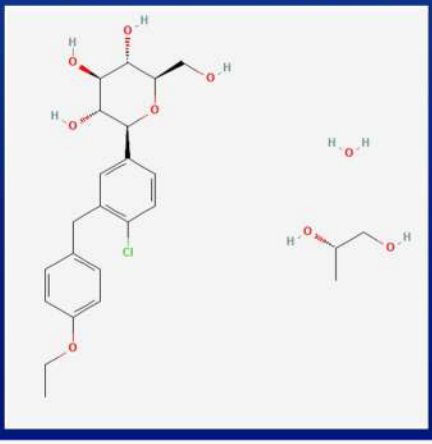
Mechanism Of Action:

Linagliptin is a competitive, reversible DPP-4 inhibitor. Inhibition of this enzyme slows the breakdown of GLP-1 and glucose-dependant insulinotropic polypeptide (GIP). GLP-1 and GIP stimulate the release of insulin from beta cells in the pancreas while inhibiting release of glucagon from pancreatic beta cells. These effects together reduce the breakdown of glycogen in the liver and increase insulin release in response to glucose.

Indication:

Linagliptin is used as monotherapy, or in combination with other antidiabetic medicines including insulin, for treatment of type 2 diabetes.

Dapagliflozin propanediol monohydrate



Chemical information

IUPAC name
(2S)-propane-1,2-diol
(2S,3R,4R,5S,6R)-2-{4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl}
-6-(hydroxymethyl)oxane-3,4,5-triol hydrate

CAS No.
960404-48-2

Molecular Weight
502.9 g·mol−1

Molecular Formula
C24H37ClO10

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Mechanism Of Action:

Dapagliflozin inhibits the sodium-glucose contransporter 2(SGLT2) which is primarily located in the proximal tubule of the nephron. SGLT2 facilitates 90% of glucose resorption in the kidneys and so its inhibition allows for glucose to be excreted in the urine. This excretion allows for better glycemic control and potentially weight loss in patients with type 2 diabetes mellitus.

Indication:

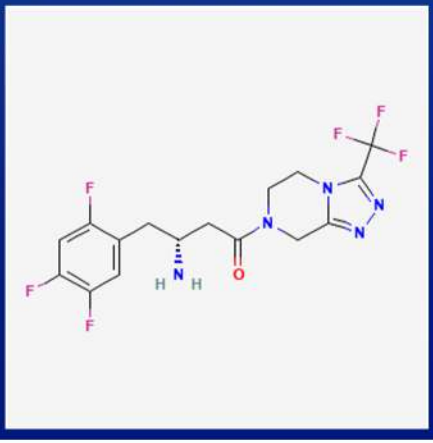
• Dapagliflozin is indicated to be used as monotherapy or in combination with insulin or other antidiabetic medicines in adult patients with type 2 diabetes mellitus.

• For reducing the risk of cardiovascular death and hospitalization in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

• For reducing the risk of cardiovascular death and hospitalization in adult patients with heart failure with reduced ejection fraction.

• Dapagliflozin can also be used for reducing the risk of end-stage kidney disease (ESKD) and hospitalization or death from heart problems in adult patients who also have kidney problems caused by type 2 diabetes.

SITAGLIPTIN PHOSPHATE MONOHYDRATE



Chemical information

IUPAC name
(R)-4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine

CAS No.
654671-77-9

Molecular Weight
407.314 g/mol

Molecular Formula
C16H15F6N5O

Mechanism Of Action:

Sitagliptin functions by stimulating insulin production and reducing the excessive production of glucose in the liver. It achieves this by prolonging the action of GLP-1 and GIP, which are active incretin hormones. The elevation of these incretin levels by sitagliptin leads to increased insulin production and decreased glucagon secretion from alpha cells. Consequently, this inhibits the liver's excessive production of glucose, contributing to improved glucose control.

Indication:

- Type 2 Diabetes Mellitus

Sitagliptin is indicated as a monotherapy to be used alongside diet and exercise for the purpose of enhancing glycemic control in patients diagnosed with type 2 diabetes mellitus. Additionally, it is prescribed in combination with immediate or extended-release metformin, either as separate medications or in the form of fixed combinations such as Janumet or Janumet XR. This combination therapy is recommended as an adjunct to diet and exercise to further improve glycemic control in patients with type 2 diabetes mellitus when the use of both sitagliptin and metformin is deemed appropriate.

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- Teriflunomide
- Dimethyl fumarate
- Fingolimod
- Diroximel Fumarate
- Sipinimod
- Monomethyl Fumarate
- Ozanimod

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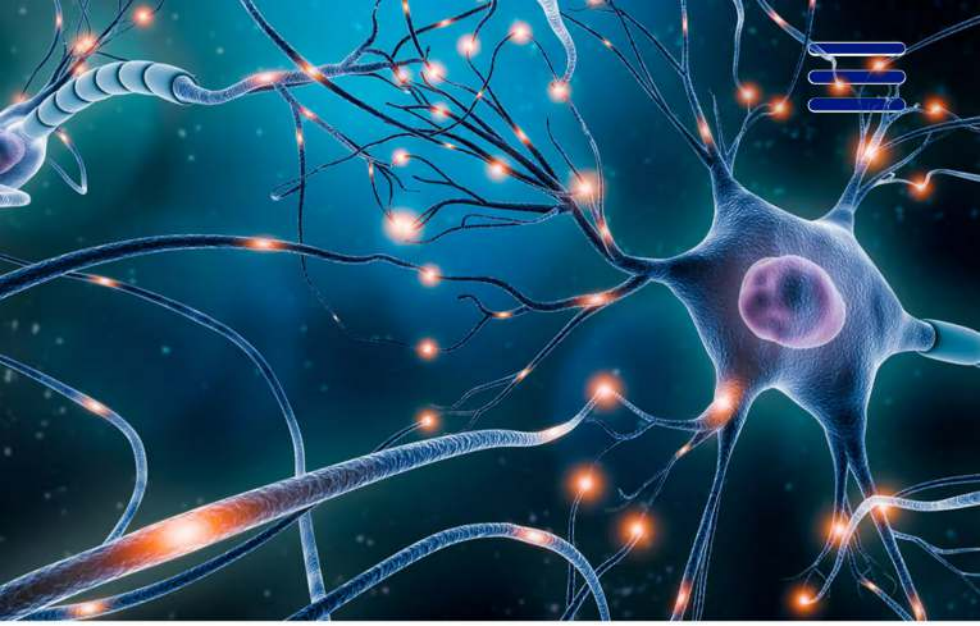
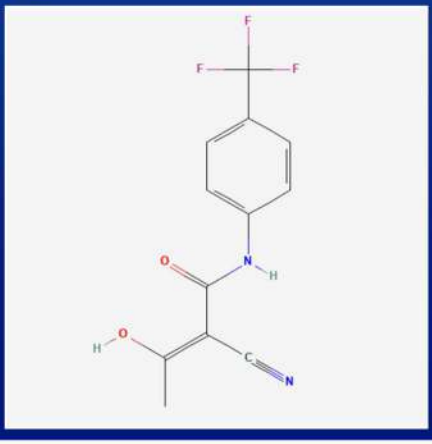


Multiple sclerosis represents a health condition in which immune system attacks the protective barrier (myelin) that covers nerve fibers and causes potentially disabling problems. Patients are usually affected by Multiple sclerosis at a highly productive stage of life, when people are building careers and planning families. MS can have a significant impact on affected individuals as much as their families and society.

According to National Multiple sclerosis (MS) Society study estimate, about one million people in the U.S are affected by Multiple sclerosis, which is much higher than the first national research on MS prevalence since 1975 and the last reported number. Also has been reported that 2.3 million people live with Multiple sclerosis worldwide and about 200 new cases are being diagnosed each week in the US.

Although there is a lack of ultimate cure for Multiple sclerosis, but our growing knowledge in disease-modifying therapies can make an opportunity for patients to reduce disability and extend chance of survival.

Teriflunomide



Chemical information

IUPAC name
(Z)-2-cyano-3-hydroxy-N-[4-(trifluoromethyl)phenyl]but-2-enamide

CAS No.
163451-81-8

Molecular Weight
270.21 g·mol−1

Molecular Formula
C12H9F3N2O2

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

It's a selective and reversible inhibitor of dihydro-orotate dehydrogenase, which is a key mitochondrial enzyme in the de novo pyrimidine synthesis pathway, leading to a reduction in proliferation of activated B and T lymphocytes without causing cell death.

Indication:

Teriflunomide is used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Dimethyl fumarate

Chemical information

IUPAC name
Dimethyl (E)-but-2-enedioate

CAS No.
624-49-7

Molecular Weight
144.12 g·mol−1

Molecular Formula
C6H8O4

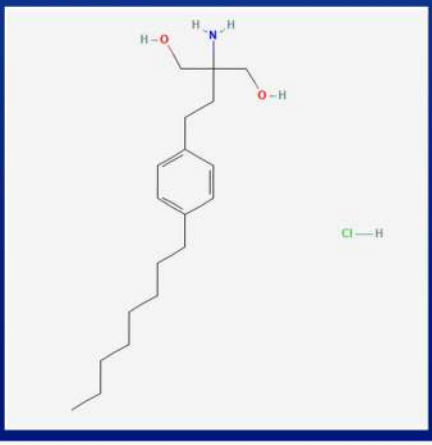
Mechanism Of Action:

It acts centrally by activating the nuclear factor erythroid 2 related factor 2 (Nrf2) transcriptional pathway, which regulates enzymes that reduce oxidative stress. And may enhance the Nrf2 transcriptional pathway within the CNS, but this is unproven.

Indication:

Dimethyl fumarate is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Fingolimod Hydrochloride



Chemical information

IUPAC name
2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol;hydrochloride

CAS No.
162359-56-0

Molecular Weight
343.9 g·mol−1

Molecular Formula
C19H34ClNO2

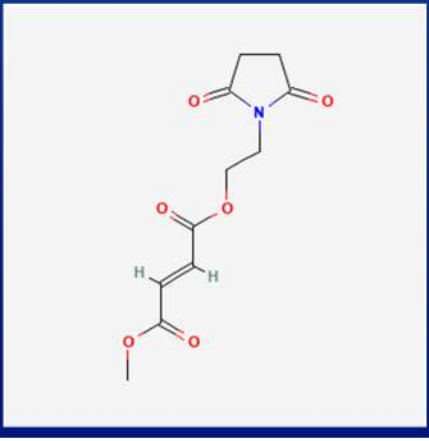
Mechanism Of Action:

Active form of fingolimod binds to sphingosine 1-phosphate receptors 1, 3, 4, and 5. And blocks the lymphocytes' ability to emerge from lymph nodes; therefore, the number of lymphocytes available to the CNS is decreased, which reduces central inflammation.

Indication:

Fingolimod is indicated for the treatment of relapsing types of MS including: clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease, in patients ≥10 years of age.

DIROXIMEL FUMARATE



Chemical information

IUPAC name
dimethyl (E)-but-2-enedioate

CAS No.
1577222-14-0

Molecular Weight
130.099 g/mol

Molecular Formula
C5H6O4

Mechanism Of Action:

Diroximel fumarate is believed to modulate cell signaling pathways, leading to favorable immune and neuroprotective effects. Monomethyl fumarate (MMF) serves as the active metabolite of diroximel fumarate and triggers the activation of the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in humans. This pathway is known to respond to oxidative stress within cells.

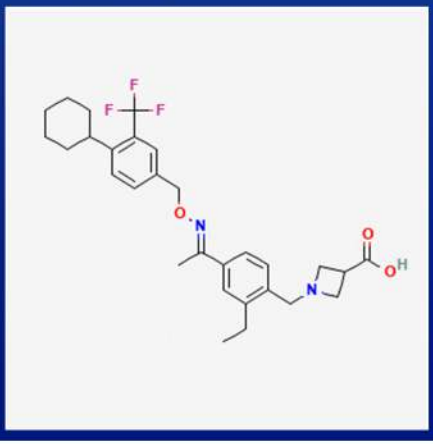
Indication:

•Multiple Sclerosis

This medication is used to treat relapsing forms of multiple sclerosis (MS), which include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Diroximel fumarate undergoes metabolism to produce the pharmacologically active metabolite, monomethyl fumarate (MMF), which is also found in dimethyl fumarate. Therefore, the effectiveness of diroximel fumarate is based on its established bioequivalence to dimethyl fumarate. It is expected that diroximel fumarate will exhibit similar efficacy and safety profiles as dimethyl fumarate, which has demonstrated significant reductions in relapse rates and the occurrence of new or enlarging T2 lesions.

SIPONIMOD FUMARATE



Chemical information

IUPAC name
1-{{4-[(1E)-1-({[4-Cyclohexyl- 3-(trifluoromethyl)phenyl]methoxy}imino)ethyl]-2-ethylphenyl}methyl}azetidine-3-carboxylic acid

CAS No.
1234627-85-0

Molecular Weight
516.605 g/mol

Molecular Formula
C29H35F3N2O3

Mechanism Of Action:

Siponimod works through a mechanism of action as a selective modulator of sphingosine 1-phosphate receptors (S1P). Specifically, it binds to S1P subtypes 1 and 5, acting as a functional antagonist. By binding to S1P1, it triggers the internalization and degradation of the receptor in T and B cells. This mechanism helps regulate the function of these cells and contributes to the therapeutic effects of siponimod.

Indication:

•Multiple Sclerosis

The treatment of relapsing forms of multiple sclerosis (MS), which encompass clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, involves the use of various disease-modifying therapies. Siponimod is among these therapies and is utilized in the management of relapsing forms of MS. While these treatments do not offer a cure for MS, they have demonstrated effectiveness in modifying several indicators of disease activity, such as reducing relapse rates, preventing the formation of new or enhancing MRI lesions, and slowing down disability progression.

MONOMETHYL FUMARATE

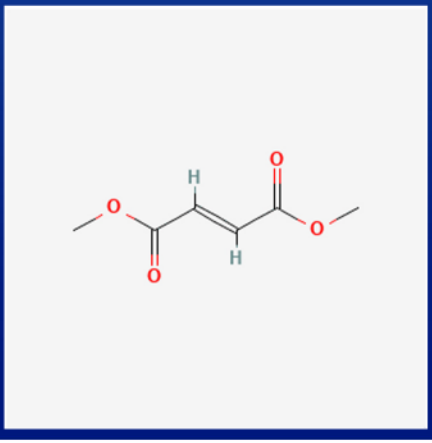
Chemical information

IUPAC name
(2E)-4-methoxy-4-oxobut-2-enoic acid

CAS No.
2756-87-8

Molecular Weight
130.099 g/mol

Molecular Formula
C5H6O4



Mechanism Of Action:

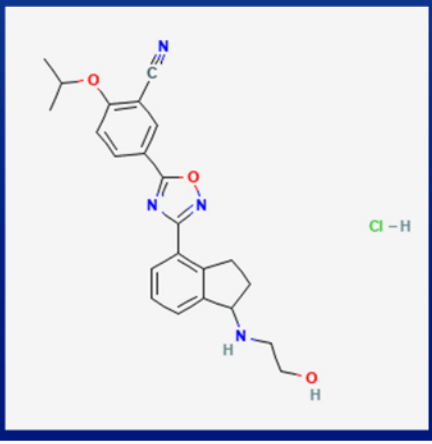
Monomethyl fumarate (MMF) is the active metabolite of diroximel fumarate. It has the ability to activate the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway in humans. This particular pathway is activated in response to oxidative stress in cells. Additionally, in laboratory studies, MMF has shown to function as a nicotinic acid receptor agonist.

- **Indication:**

Multiple Sclerosis

It is used for the treatment of relapsing forms of multiple sclerosis (MS), which include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. MMF is the active metabolite of dimethyl fumarate, and its use is supported by evidence of bioequivalence to dimethyl fumarate as well as previous efficacy and safety findings with the latter. Studies have demonstrated that dimethyl fumarate significantly reduces relapse rates and the formation of new or enlarging T2 lesions in patients with MS.

OZANIMOD HYDROCHLORIDE



Chemical information

IUPAC name
5-(3-{(1S)-1-[(2-Hydroxyethyl)amino]-2,3-dihydro-1H-inden-4-yl}-1,2,4-oxadiazol-5-yl)-2-isopropoxybenzonitrile

CAS No.
1618636-37-5

Molecular Weight
404.46 g/mol

Molecular Formula
C23H24N4O3

Mechanism Of Action:

Ozanimod is a specific modulator of S1P receptors that selectively binds to S1P1R and S1P5R subtypes. While the exact mechanism of action of ozanimod is not fully elucidated, it is believed to impede the movement of lymphocytes, which typically contribute to the inflammation observed in multiple sclerosis (MS). By reducing lymphocyte migration, ozanimod potentially alleviates the inflammatory response associated with MS.

Indication:

Multiple Sclerosis

The treatment of relapsing forms of multiple sclerosis (MS), such as clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, involves various disease-modifying therapies. One of these therapies is ozanimod. While these treatments cannot cure MS, they have demonstrated the ability to modify various indicators of disease activity, including relapse rates, the presence of new or worsening lesions on MRI scans, and the progression of disability.

Ulcerative Colitis

The treatment of moderate to severely active ulcerative colitis (UC) in adults aims to achieve and sustain remission without the use of corticosteroids and promote healing of the intestinal lining. These goals are essential in the management of ulcerative colitis.

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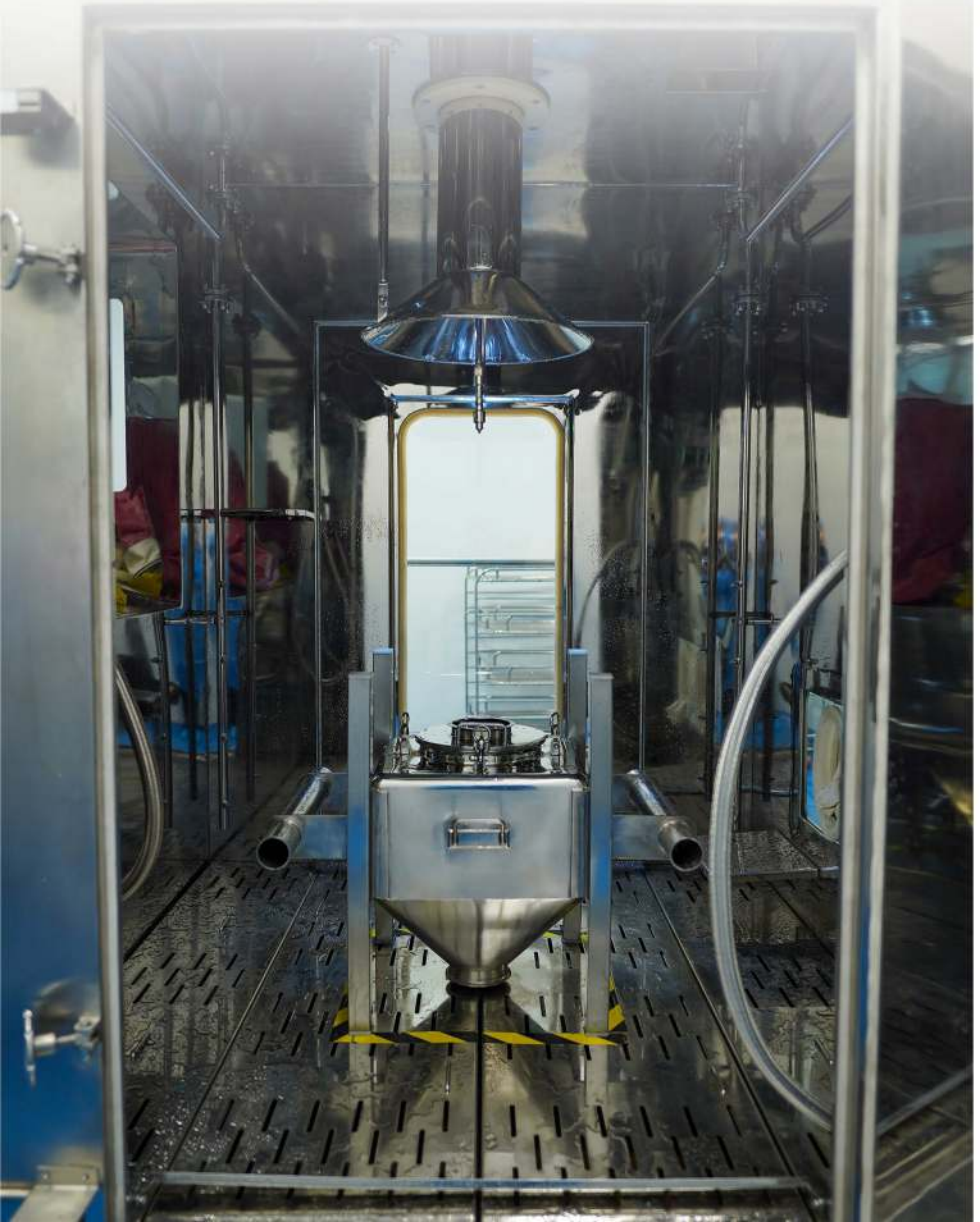


Apixaban .....➤

Rivaroxaban .....➤

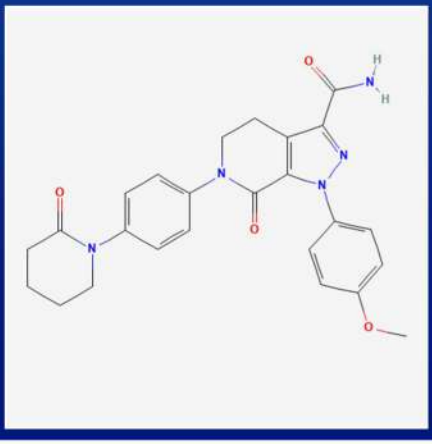
Sacubitril-Valsartan .....➤

Ticagrelor .....➤

Parsian pharmaceutical co

Thrombosis occurs when a blood clot forms inside a blood vessel, thrombosis causes blocking of the blood flow through the circulatory system and leads to serious health issues. Mostly the pathology pathway of ischemic heart disease and ischemic stroke is attributed to thrombosis, which makes thrombosis as one of the most important cause of cardiovascular diseases. Cardiovascular diseases (CVDs) represent a group of disorders of the heart and blood vessels. Some CVDs which thrombosis is a potential cause of them are: coronary heart disease, cerebrovascular disease and peripheral arterial disease. An estimation has reported that about 17.9 million deaths each year are underlying by cardiovascular diseases, which make cardiovascular diseases (CVDs) the leading cause of death globally. Direct oral anticoagulants (DOACs) are prescribed for prevention and treatment of various cardiovascular diseases (CVDs). Recently direct oral anticoagulants (DOACs) are becoming interesting alternatives to the traditional standard of care in anticoagulation, vitamin K antagonist. Prior to 2010, the only approved oral anticoagulant on the market was warfarin, but since then that the first DOACs were approved, led DOACs to be as a leading therapeutic option, due to their better safety and effectiveness which make them more convenient treatment options for patients and clinicians in thromboembolic settings.

Apixaban



Chemical information

IUPAC name
1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxopiperidin-1-yl)phenyl]-4,5-dihydropyrazolo[3,4-c]pyridine-3-carboxamide

CAS No.
503612-47-3

Molecular Weight
459.5 g·mol−1

Molecular Formula
C25H25N5O4

Mechanism Of Action:

It's a highly selective and reversible direct inhibitor of free and clot-bound factor Xa, the final enzyme in the coagulation cascade that is responsible for fibrin clot formation. FXa catalyzes the conversion of prothrombin to thrombin.

Indication:

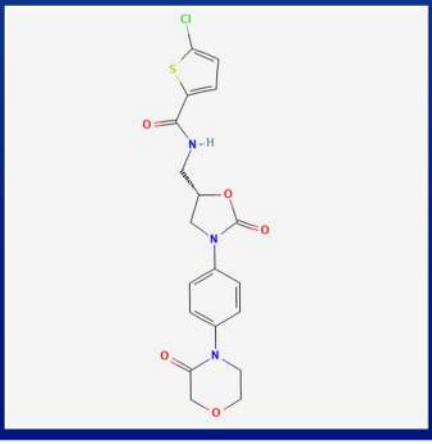
- Prophylaxis of venous thromboembolism following knee or hip replacement surgery.

- Treatment of Deep Vein Thrombosis (DVT) & Pulmonary Embolism (PE).

- Prophylaxis of recurrent DVT and PE.

- Prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation and at least one risk factor (such as previous stroke or transient ischemic attack, symptomatic heart failure, diabetes mellitus, hypertension, or age 75 years and over).

Rivaroxaban



Chemical information

IUPAC name
5-chloro-N-[[(5S)-2-oxo-3-[4-(3-oxomorpholin-4-yl)phenyl]-1,3-oxazolidin-5-yl]methyl]thiophene-2-carboxamide

CAS No.
366789-02-8

Molecular Weight
435.9 g·mol−1

Molecular Formula
C19H18ClN3O5S

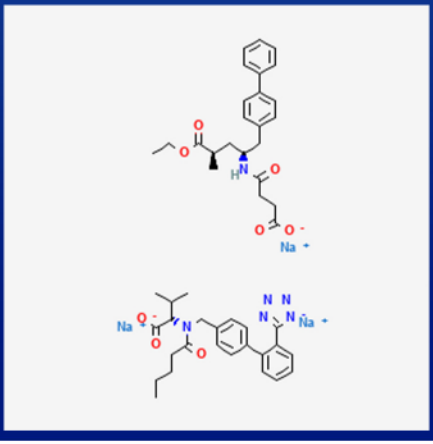
Mechanism Of Action:

It's a selective inhibitor of factor Xa (FXa), and is an inhibitor of free FXa and prothrombinase activity, and indirectly inhibits platelet aggregation induced by thrombin.

Indication:

- Reduction of Risk of Stroke and Systemic Embolism in Non-valvular Atrial Fibrillation (NVAF)
- Treatment of Deep Vein Thrombosis (DVT) & Pulmonary Embolism (PE)
- Reduction in the Risk of Recurrence of DVT and/or PE
- Prophylaxis of DVT Following Hip or Knee Replacement Surgery
- Prophylaxis of Venous Thromboembolism in Acutely Ill Medical Patients at Risk for Thromboembolic Complications Not At High Risk of Bleeding
- Reduction of Risk of Major Cardiovascular Events in Patients with Chronic Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD)
- Treatment of venous thromboembolism, and Prophylaxis of recurrent venous thromboembolism in in pediatric patients.

Sacubitril-Valsartan



Chemical information

IUPAC name
hexasodium;4-[[(2S,4R)-5-ethoxy-4-methyl-5-oxo-1-(4-phenylphenyl)pentan-2-yl]amino]-4-oxobutanoate;(2S)-3-methyl-2-[pentanoyl-[[4-[2-(1,2,3-triaza-4-azanidacyclopenta-2,5-dien-5-yl)phenyl]phenyl]methyl]amino]butanoate;pentahydrate

CAS No.
936623-90-4

Molecular Weight
915.98 g/mol

Molecular Formula
C96H120N12Na6O21

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ready to press ☑

Mechanism Of Action:

Sacubitril/valsartan is a medication that exerts its effects through the dual inhibition of neprilysin, an enzyme responsible for degrading certain peptides, and the angiotensin II type-I receptor (AT1 receptor). This unique combination leads to an increase in the levels of peptides that would otherwise be degraded by neprilysin.

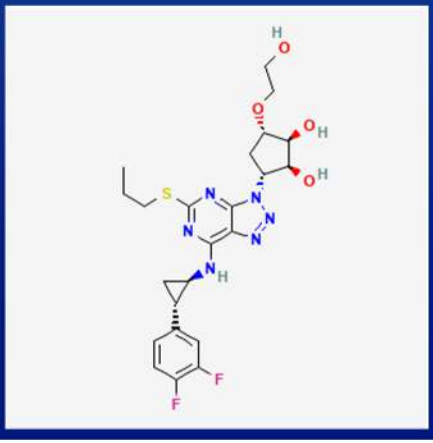
The drug's neprilysin inhibition prevents the breakdown of beneficial peptides, allowing them to accumulate in the body. Meanwhile, valsartan specifically blocks the AT1 receptor, preventing the harmful effects of angiotensin II. Additionally, valsartan helps inhibit the release of angiotensin II, further contributing to its beneficial effects.

Indication:

•Heart Failure

The fixed combination of sacubitril/valsartan is prescribed to reduce the risk of cardiovascular death and hospitalization for heart failure in patients suffering from chronic heart failure with reduced ejection fraction and classified as NYHA class II–IV. This medication is typically administered in combination with other heart failure therapies, such as β-adrenergic blocking agents, aldosterone antagonists, and diuretics. It can also be used as a substitute for therapy involving an ACE inhibitor or other angiotensin II receptor antagonists.

TICAGRELOR



Chemical information

IUPAC name
(1S,2S,3R,5S)-3-[7-[(1R,2S)-2-(3,4-Difluorophenyl)cyclopropylamino]-5-(propylthio)-3H-[1,2,3]triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)cyclopentane-1,2-diol

CAS No.
274693-27-5

Molecular Weight
522.567 g/mol

Molecular Formula
C23H28F2N6O4S

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

Ticagrelor exerts its pharmacological effects by binding to a specific site on the P2Y12 receptor, which is different from the ADP binding site. By reversibly binding to the ADP P2Y12 receptor, BRILINTA effectively inhibits the binding of ADP molecules. As a result, signal transduction and platelet activation, which can potentially contribute to the formation of pathological blood clots (thrombus), are prevented.

Indication:

•Acute Coronary Syndrome or History of MI

When used together with aspirin, ticagrelor is indicated for reducing the risk of cardiovascular death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS). This combination therapy has been shown to effectively lower the incidence of adverse cardiovascular events in this patient population.

•Coronary Artery Disease but No Prior Stroke or MI

The medication is prescribed to decrease the risk of an initial myocardial infarction (MI) or stroke in individuals with established coronary artery disease (CAD) who are considered to be at high risk for such thrombotic cardiovascular events. Its use in this patient population has been demonstrated to effectively mitigate the occurrence of these adverse outcomes

•Acute Ischemic Stroke or Transient Ischemic Attack

The medication is administered to minimize the risk of stroke in patients who have experienced an acute ischemic stroke with a National Institutes of Health Stroke Scale (NIHSS) score of 5 or less, or in those who have had a high-risk transient ischemic attack (TIA). By utilizing this treatment, the likelihood of subsequent stroke occurrences is effectively reduced in these individuals.

Riluzole ·····➤

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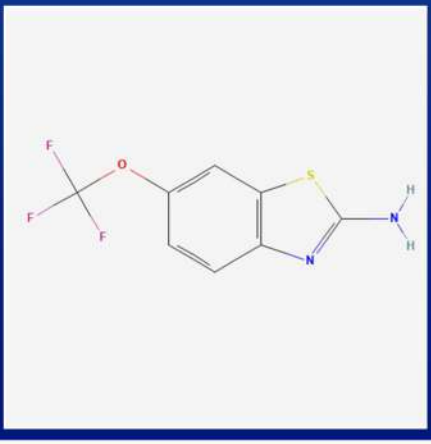
Amyotrophic Lateral Sclerosis (ALS) represents a progressive neuromuscular disease, often is referred to as a syndrome since the disease becomes apparent in various patterns. ALS occurrence is spontaneous and is characterized by a progressive degeneration of motor nerve cells which control voluntary muscles in the brain (upper motor neurons) and spinal cord (lower motor neurons). ALS is commonly known as Lou Gehrig's disease. The motor neurons can no longer send impulses to the muscles, which lead to muscles atrophy and increased muscle weakness. ALS can affect anyone worldwide with no ethnic, racial or socioeconomic boundaries. In general, most patients are being diagnosed at ages of between 40 and 70, with the average of being 55 years old. The number of patients who have been affected by ALS is as many as 30,000 in the U.S, also 5,000 new cases are being diagnosed each year. According to estimates, more than five of every 100,000 deaths in people aged 20 or above are attributed to Amyotrophic Lateral Sclerosis (ALS). The prevalence incidence of ALS is about equal to multiple sclerosis and five times higher than Huntington's disease. Up to now only four drugs have FDA-approval to treat ALS; Riluzole, Radicava, Nuedexta and Tiglutik. The one and only medicine that has been noticed in the American Academy of Neurology (AAN) guideline regarding management and care of the patient with amyotrophic lateral sclerosis (ALS), is Riluzole. The only medication that has shown efficacy in extending life in Amyotrophic Lateral Sclerosis (ALS), is Riluzole. Riluzole's mechanism of action is not known. Pharmacologic properties include inactivation of voltage-dependent sodium channels, inhibitory effect on glutamate release and ability to interfere with intracellular events that follow transmitter binding at excitatory amino acid receptors.

Riluzole



Chemical information

IUPAC name
6-(trifluoromethoxy)-1,3-benzothiazol-2-amine

CAS No.
1744-22-5

Molecular Weight
234.20 g·mol−1

Molecular Formula
C8H5F3N2OS

Mechanism Of Action:

The mode of action of riluzole is unknown. Its pharmacological properties include the following, some of which may be related to its effect: 1) an inhibitory effect on glutamate release (activation of glutamate reuptake), 2) inactivation of voltage-dependent sodium channels, and 3) ability to interfere with intracellular events that follow transmitter binding at excitatory amino acid receptors.

Indication:

Riluzole is indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

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Tofacitinib ➤

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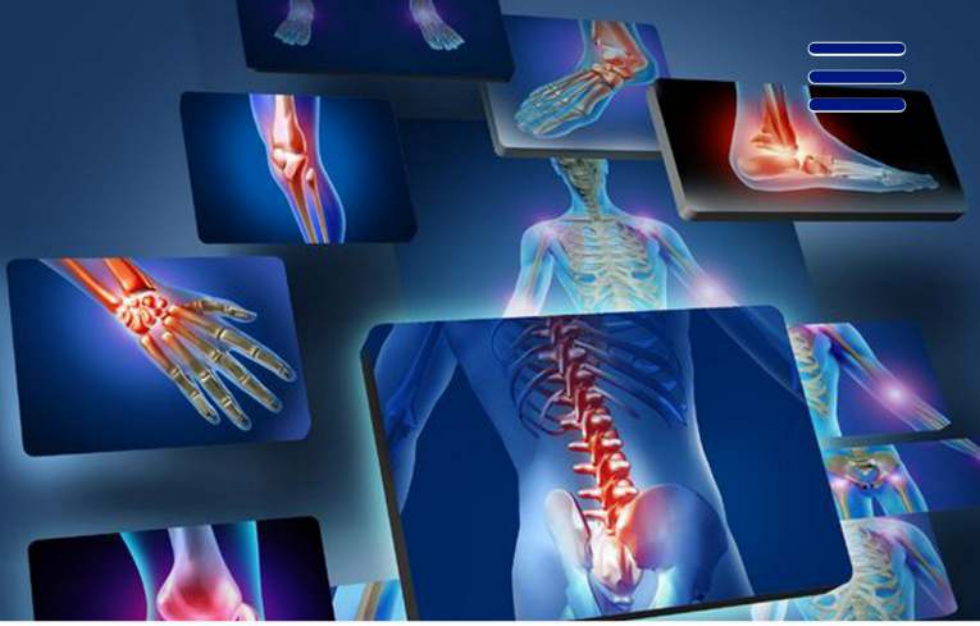
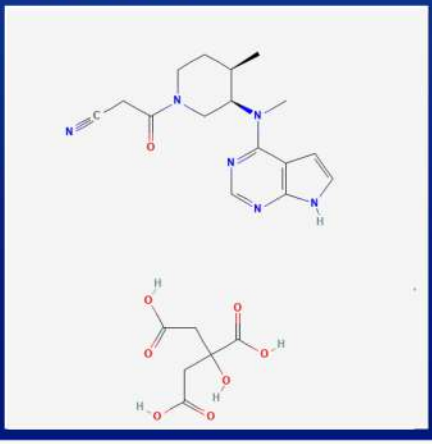


Rheumatoid Arthritis is a systemic disease, occurs when immune system mistakenly attacks its own healthy cells, especially the lining of the joints which named by synovium or synovial membrane. Rheumatoid Arthritis affects the lining of your joints, causing a chronic painful swelling that can eventually result in joint deformity and bone erosion. Rheumatoid arthritis (RA) represents a chronic inflammatory disease that can attack more than just your joints. Sometimes Rheumatoid Arthritis's inflammation can damage the other part of body as well, the eyes, skin, lungs, blood vessels and heart. The disease can lead to disability, decreased quality of life and premature mortality due to joint deformity and bone erosion. Each year 71 out of 100,000 persons are being diagnosed with Rheumatoid Arthritis, according to an estimate 1.5 million Americans are dealing with Rheumatoid Arthritis. Estimates show that prevalence incidence of Rheumatoid Arthritis in women is 2 or 3 times higher than men, which may it's due to differential sexual hormones levels that play an important role in triggering or preventing it. Women generally are being diagnosed with RA between the ages of 30 and 60, which is a little bite later in men. However, Rheumatoid arthritis can present at any age, even children can develop it. Based on European Alliance of Associations for Rheumatology recommendations, following failure of one or more conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) and in the presence of at least one poor prognostic factor, a biological DMARD (bDMARD) or a Janus kinase (JAK) inhibitor should be started. Tofacitinib is an oral Janus kinase (JAK) inhibitor which is approved for the treatment of RA.

Tofacitinib citrate



Chemical information

IUPAC name
2-hydroxypropane-1,2,3-tricarboxylic acid;3-[(3R,4R)-4-methyl-3-[methyl(7H-pyrrolo[2,3-d]pyrimidin-4-yl)amino]piperidin-1-yl]-3-oxopropanenitrile

CAS No.
540737-29-9

Molecular Weight
504.5 g·mol−1

Molecular Formula
C22H28N6O8

Granule Available
ready to fill ☐
ready to press ☑

Mechanism Of Action:

Tofacitinib exerts its mechanism of action by inhibiting intracellular cytoplasmic non-receptor tyrosine kinase JAK enzymes, which are involved in adaptive and innate immune reactions in the process of immune-mediated inflammatory diseases. It is a reversible and competitive JAK inhibitor that binds to the ATP binding site of the kinase domain of JAK. It is similar in structure to ATP and binds to the ATP-binding site of JAK, thus competing with ATP for binding to the active site of the kinase domain. As a result, the drug inhibits the phosphorylation and activation of JAK, thereby preventing the phosphorylation and activation of STATs, and thus the activation of gene transcription; this leads to decreased cytokine production and modulation of the immune response. Tofacitinib is a pan-JAK inhibitor but targets JAK1 and JAK3 with a higher specificity over JAK2 and TYK2.

Indication:

Tofacitinib is used to treat adults who have tried TNF blockers with:

- Moderately to severely active rheumatoid arthritis when one or more medicines called tumor necrosis factor (TNF) blockers have been tried, and did not work well or cannot be tolerated.
- Active psoriatic arthritis when one or more TNF blocker medicines have been tried, and did not work well or cannot be tolerated.
- Moderately to severely active ulcerative colitis when one or more TNF blocker medicines have been tried, and did not work well or cannot be tolerated.
- Active ankylosing spondylitis when one or more TNF blocker medicines have been tried, and did not work well or cannot be tolerated.

Tofacitinib Oral Solution is used to treat patients 2 years of age and older with:

- Active polyarticular course juvenile arthritis when one or more TNF blocker medicines have been tried, and did not work well or cannot be tolerated.

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Roxadustat

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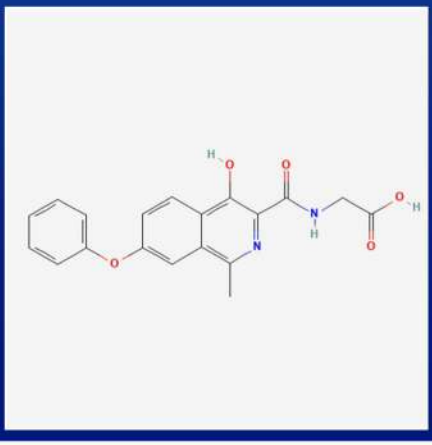
Anemia can develop a life threatening health condition in which the number of red blood cells and the hemoglobin concentration is insufficient. Hemoglobin is the main component of RBCs, which is a protein that carries oxygen to cells throughout the body. RBC synthesis takes place in the bone marrow, under the control of erythropoietin (EPO) produced by interstitial fibroblasts in the kidney. Anemia can lead to shortness of breath, cognitive dysfunction, significant fatigue, and decreased quality of life, which is associated with increased risk of cardiovascular complications, hospitalization, and death. Severe anemia is common in patients who are dealing with cancer, CKD, inflammatory diseases, myelodysplastic syndrome (MDS) and other serious health conditions. Anemia is a life threatening public health condition which specially affects young children and pregnant women. According to World Health Organization (WHO) estimates, 1.62 million people are affected by anemia, which is about 24.8% of the population globally. The highest prevalence tends to be in children less than 5 years of age, women of reproductive age and pregnant women. According to a global estimate, around 42percent of preschool-age children (i.e. those aged 6–59 months) and 40percent of pregnant women worldwide are dealing with anemia. Roxadustat could be the first in a new class of treatments called oral HIF-PH inhibitors that promotes RBC production or erythropoiesis, through increased endogenous production of EPO. Roxadustat is also in clinical development for chemotherapy-induced anemia and anemia related to MDS. Roxadustat is approved in China, Japan, Chile and South Korea, for the treatment of anemia in CKD patients. In Europe, It's under final regulatory review following a positive EU CHMP opinion in June 2021.

Roxadustat is being commercialized and developed for the potential treatment of anemia within the US and other countries within the Americas and Australia, New Zealand and China, as well as Southeast Asia, and also is being worked for the potential treatment of anemia in Europe, Russia, Japan, Turkey and also the Commonwealth of Independent States, South Africa and therefore the Middle East.

Roxadustat



Chemical information

IUPAC name
2-[(4-hydroxy-1-methyl-7-phenoxyisoquinoline-3-carbonyl)amino]acetic acid

CAS No.
808118-40-3

Molecular Weight
352.3 g·mol−1

Molecular Formula
C19H16N2O5

Mechanism Of Action:

Anemia is a common complication of chronic kidney disease that may be caused by reduced production of renal erythropoietin (EPO), functional iron deficiency due to increased levels of hepcidin, blood loss, reduced erythrocyte survival duration, and inflammation. Hypoxia-inducible factor (HIF) is a transcription factor that induces several target oxygen-sensitive genes in response to low oxygen levels in the cellular environment, or hypoxia. Target genes are involved in erythropoiesis, such as those for EPO, EPO receptor, proteins promoting iron absorption, iron transport, and haem synthesis. Activation of the HIF pathway is an important adaptive responsive to hypoxia to increase red blood cell production. HIF is heterodimeric and contains an oxygen-regulated α-subunit. The α-subunit houses an oxygen-dependent degradation (ODD) domain that is regulated and hydroxylated by HIF-prolyl hydroxylase (HIF-PHD) enzymes under normoxic cellular conditions. HIF-PHD enzymes play a crucial role in maintaining a balance between oxygen availability and HIF activity.

Roxadustat is a reversible and potent inhibitor of HIF-PHD enzymes: inhibition of HIF-PHD leads to the accumulation of functional HIF, an increase in plasma endogenous EPO production, enhanced erythropoiesis, and indirect suppression of hepcidin, which is an iron regulator protein that is increased during inflammation in chronic kidney disease. Roxadustat can also regulate iron transporter proteins and regulates iron metabolism by increasing serum transferrin, intestinal iron absorption and the release of stored iron in patients with anemia associated with dialysis-dependent or dialysis-independent CKD. Overall, roxadustat improves iron bioavailability, increases Hb production, and increases red cell mass.

Indication:

Roxadustat is indicated for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease (CKD).

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Our Certificate

Next

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Export GMP for all of the Products

ISLAMIC REPUBLIC OF IRAN
MINISTRY OF HEALTH AND MEDICAL EDUCATION

FOOD AND DRUG ADMINISTRATION

REF: 665/44455
Date: 31/10/2021

Manufacturer: Phanavaran Parsian Pharmaceutical Co.
Address: Baharestan Industrial Zone, Alborz, Iran.

Production Lines: *General API:* Empagliflozin, Erlotinib Hydrochloride, Nilotinib Hydrochloride Monohydrate and Riluzole
Hazardous API: Dimethyl Fumarate, Teriflunomide, Imatinib Mesylate, Letrozole, Sorafenib Tosylate, Sunitinib Malate, Ibrutinib, Palbociclib, Pazopanib Hydrochloride, Regorafenib Monohydrate, Dasatinib Monohydrate, Dasatinib Anhydrous, Favipiravir, Gefitinib, Rivaroxaban, Osimertinib Mesylate, Vandetanib, Tofacitinib Citrate, Fingolimod and Dapagliflozin Propanediol Monohydrate
Hazardous Granule: Erlotinib Granule, Imatinib Granule, Nilotinib Granule, Sunitinib Malate Granule, Ibrutinib Granule, Palbociclib Granule, Pazopanib HCl Granule, Regorafenib Monohydrate Granule, Osimertinib Mesylate Granule, Vandetanib Granule and Tofacitinib Citrate Granule

This is to certify that above-mentioned production lines were duly inspected and approved in accordance with Good Manufacturing Practice Principles for active pharmaceutical ingredients which are currently in force in the I.R of Iran.

The manufacturer plant is subject to regular GMP inspections based on PIC/S regulations (at suitable intervals) by the Iranian Food and Drug Administration.

The production lines of *General API, Hazardous API and Hazardous Granule* ***are in compliance with the cGMP/GMP standards and relevant principles and regulation and complies with the Good Manufacturing Practice requirements of the PIC/S Guidelines.***

This certificate is valid for one year.

Dr.Heydar Mohammadi
Director General

Add.: FOOD AND DRUG ADMINISTRATION Bldg.,
FAKHR-E-RAZI St., ENGHELAB Ave.,
TEHRAN 1314715311, I. R. IRAN

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FAX: +98-21-66460142
WEBSITE: http://fda.gov.ir
E-Mail: ceo@fda.gov.ir

Parsian pharmaceutical co

Parsian
Pharmaceutical Co.

GMP Certificates for Production Line of Hazardous API

Islamic Republic Of Iran
Ministry Of Health & Medical Education

FOOD AND DRUG ADMINISTRATION

GMP Certificate

Certificate Code :	PRM-99-03	PRM-99-03	کد گواهی:
Company Name:	Parsian Pharmaceutical Co.	فناوران دارویی پارسیان	نام شرکت:
Activity :	API & Granule Production	تولید مواد اولیه دارویی و گرانول	فعالیت:
Authorised Person:	Dr. Abeh Rahimi	دکتر عطیه رحیمی	مسوول فنی:
Date Of Establishment License :	2020-10-11	۱۳۹۹/۰۷/۲۰	تاریخ پروانه تاسیس:
Establishment No :	665/68739	۶۶۵/۶۸۷۳۹	شماره پروانه تاسیس:
Country :	Iran	ایران	کشور:
Address :	No.153, 5th west golestan, Baharestan Industrial Zone, Alborz, Iran.	استان البرز-شهرک صنعتی بهارستان - گلستان پنجم غربی -پلاک ۱۵۳	نشانی:
Telephone :	026-91004245	۰۲۶-۹۱۰۰۴۲۴۵	تلفن:
Inspected Line:	Hazardous APIs	مواد اولیه پرخطر	خط بازدید شده:
Product Name :	Letrozole, Imatinib Mesylate, Sunitinib malate, Dimethyl fumarate, Erlotinib HCl, Sorafenib Tosylate, Nilotinib HCl monohydrate, Teriflunomide, Rivaroxaban, Gefitinib, Lenalidomide hemihydrate, Ibrutinib, Palbociclib, Dasatinib monohydrate, Dasatinib anhydrous, Tofacitinib citrate, Favipiravir, Pazopanib HCl, Fingolimod	لترزول، ایماتینیب مزیلات، سونیتینیب مالات، دی متیل فومارات، ارلوتینیب هیدروکلراید، سورافینیب توسیلات، نیلوتینیب هیدروکلراید مونو هیدرات، تری فلونومید، ریواروکسابان، جفیتینیب، لنالیدومید همی هیدرات، ایبروتینیب، پالبوسیکلیب، داساتینیب مونو هیدرات، داساتینیب انهیدروس، توفاسیتینیب سیترات، فاویپیراویر، پازوپانیب هیدروکلراید، فینگولیمود	نام محصول بررسی شده:
Inspector`s Name:	Dr. Shoeil Alam-Dr. Darageo- Dr. Jamal Arasteh, Seyyahnouri salad	دکتر شویل آلم- دکتر دارائی دکتر جمال آراسته، دکتر سیاحنوری سالاد	نام بازرس بازرسین:
Inspection Date :	November, 2020	آذر ماه ۱۳۹۹	تاریخ بازرسی:
Issue Date:	December,2020	دی ماه ۱۳۹۹	تاریخ صدور گواهی:
Validity Date :	December,2022	دی ماه ۱۴۰۱	تاریخ انقضای گواهی:

به دنبوسیله گواهی می شود خط تولید مواد اولیه پرخطر شرکت فوق مورد بازدید کارشناسی رسمی های بیینه تولید (GMP) قرار گرفت و با توجه به شرایط موجود مورد تایید می باشد.

This is to certify that above-mentioned production line was duly inspected and approved in accordance with Good Manufacturing Practice principles for pharmaceutical products which are currently in force in the I.R of Iran. Therefore, the production line of Hazardous APIs is in compliance with the cGMP standards and relevant principles and regulations.

Dr.Heydar Mohammadi
Director General

(IFDA)

Parsian pharmaceutical co

GMP Certificates for Production Line of General API

شماره ۶۶۵/۹۳۷۴۰
تاریخ ۱۳۹۹/۱۰/۰۷
پیوست ندارد

جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی
Islamic Republic Of Iran
Ministry Of Health & Medical Education

سازمان غذا و دارو
FOOD AND DRUG ADMINISTRATION

GMP Certificate

Certificate Code :	PRM-99-02	PRM-99-02	کد گواهی:
Company Name:	Parsian Pharmaceutical Co.	فناوران دارویی پارسیان	نام شرکت
Activity :	API & Granule Production	تولید مواد اولیه دارویی و گرانول	فعالیت:
Authorised Person:	Dr. Atieh Rahimi	دکتر عطیه رحیمی	مسئول فنی:
Date Of Establishment License :	2020-10-11	۱۳۹۹/۰۷/۲۰	تاریخ پروانه تاسیس:
Establishment No :	665/68739	۶۶۵/۶۸۷۳۹	شماره پروانه تاسیس:
Country :	Iran	ایران	کشور:
Address :	No.153, 6th west golestan, Baharestan Industrial Zone, Alborz, Iran.	استان البرز-شهرک صنعتی بهارستان-گلستان ششم غربی-پلاک ۱۵۳	نشانی:
Telephone :	(+9826)91004245	۰۲۶-۹۱۰۰۴۲۴۵	تلفن:
Inspected Line:	General APIs	مواد اولیه عمومی	خط بازدید شده:
Product Name :	Riluzole,Empagliflozin, Dapagliflozin propanediol monohydrate	ریلوزول، امپگلیفلوزین، داپاگلیفلوزین پروپاندیول مونوهیدرات	نام محصول بررسی شده:
Inspector /s Name:	Dr. Sharif Alam-Dr. Daraee-Dr. Jamal Ara-Dr. Neyshaboorinejad	دکتر شریف اعلم-دکتر دارائی-دکتر جمال آرا-دکتر نیشابوری نژاد	نام بازرس/بازرسین:
Inspection Date :	November,2020	آذر ماه ۱۳۹۹	تاریخ بازرسی:
Issue Date:	December,2020	دی ماه ۱۳۹۹	تاریخ صدور گواهی:
Validity Date :	December,2022	دی ماه ۱۴۰۱	تاریخ انقضای گواهی:

بدینوسیله گواهی می‌شود خط تولید مواد اولیه پرخطر شرکت فوق مورد بازدید کارشناسی روش‌های بهینه تولید (GMP) قرار گرفت و با توجه به شرایط موجود مورد تایید می‌باشد.

This is to certify that above-mentioned production line was duly inspected and approved in accordance with Good Manufacturing Practice principles for pharmaceutical products which are currently in force in the I.R of Iran. Therefore, the production line of Hazardous APIs is in compliance with the cGMP standards and relevant principles and regulations.

Dr.Heydar Mohammadi
Director General

(IFDA)

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FAX: +98-21-66499122
WEBSITE: http://fda.gov.ir
E-Mail:

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Pharmaceutical Co.

GMP Certificates for Production Line of Hazardous Granule

Islamic Republic Of Iran
Ministry Of Health & Medical Education

FOOD AND DRUG ADMINISTRATION

GMP Certificate

Certificate Code :	PRM-99-01	PRM-99-01	کد گواهی:
Company Name:	Parsian Pharmaceutical Co.	فناوران دارویی پارسیان	نام شرکت:
Activity :	API & Granule Production	تولید مواد اولیه دارویی و گرانول	فعالیت:
Authorised Person:	Dr. Atieh Rahimi	دکتر عطیه رحیمی	مسئول فنی:
Date Of Establishment License :	2020-10-11	۱۳۹۹/۰۷/۲۰	تاریخ پروانه تاسیس:
Establishment No. :	665/68729	۶۶۵/۶۸۷۲۹	شماره پروانه تاسیس:
Country :	Iran	ایران	کشور:
Address :	No.153, 6th west golestan, Baharestan industrial Zone, Alborz, Iran.	استان البرز-شهرک صنعتی بهارستان- گلستان ششم غربی -پلاک ۱۵۳	نشانی:
Telephone :	026-91094348	۰۲۶-۹۱۰۹۴۳۴۸	تلفن:
Inspected Line:	Hazardous Granule	گرانول پرخطر	خط بازدید شده:
Product Name :	Imatinib 52.64%, Nilotinib 52.52%, Nilotinib 47.27 %, Sunitinib 39.31 %, Sunitinib 14.66 %, Erlotinib 36.42 %, Ibrutinib 42.42 %, Palbociclib 27.77 %, Sorafenib-tosylate ready to press 74.08%, Favipiravir 66.66 %	ایماتینیب ٪۵۲.۶۴، نیلوتینیب ٪۵۲.۵، نیلوتینیب ٪۴۷.۲۷، سانیتینیب ٪۳۹.۳۱، سانیتینیب ٪۱۴.۶۶، ارلوتینیب ٪۳۶.۴۲، ایبروتینیب ٪۴۲.۴۲، پالبوسیکلیب ٪۲۷.۷۷، سورافنیب پودر آماده پرس ٪۷۴.۰۸، فاویپیراویر ٪۶۶.۶۶	محصول بررسی شده:
Inspector's Name:	Dr. Sharif Abon-Dr. Danaee- Dr. Jamal Ara- Dr. Nayebzadeh nejad	دکتر شریف اعلم -دکتر دانائی- دکتر جمال آرا -دکتر نیبزاده نژاد	نام بازرس/بازرسین:
Inspection Date :	November, 2020	آذر ماه ۱۳۹۹	تاریخ بازرسی:
Issue Date:	December,2020	دی ماه ۱۳۹۹	تاریخ صدور گواهی:
Validity Date :	December,2022	دی ماه ۱۴۰۱	تاریخ انقضای گواهی:

بدینوسیله گواهی می شود خط تولید گرانول پرخطر شرکت فوق مورد بازدید کارشناسی رویش های پیمنه تولید (GMP) قرار گرفت و با توجه به شرایط موجود مورد تایید می‌باشد.

This is to certify that above-mentioned production line was duly inspected and approved in accordance with Good Manufacturing Practice principles for pharmaceutical products which are currently enforce in the I.R of Iran. Therefore, the production line of Hazardous Granules is in compliance with the cGMP standards and relevant principles and regulations.

Dr.Heydar Mohammadi
Director General

(IFDA)

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Parsian pharmaceutical co

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QC laboratory


R&D laboratory


CLIMACS
Engineering


Manufacturing
& warehouse

QC Laboratory

Parsian Pharmaceutical Co

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R&D laboratory

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R&D laboratory

Parsian Pharmaceutical Co

R&D laboratory

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Engineering

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Engineering

Parsian Pharmaceutical Co

Manufacturing & Warehouse

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Parsian Pharmaceutical Co

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