Taj Pharmaceuticals Ltd.

Montelukast Sodium

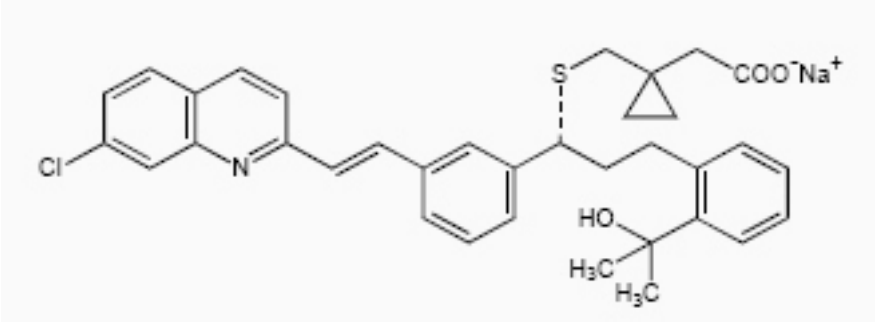
CAS No. : 158966-92-8

Systematic (IUPAC) name

2-[1-[[(1R)-1-[3-[2-(7-chloroquinolin-2-yl)ethenyl]
phenyl]-3-[2-(2-hydroxypropan-2-yl)phenyl]propyl]
sulfanylmethyl]cyclopropyl]acetic acid

Identifiers

ATC code R03DC03
PubChem 60951
DrugBank APRD00434



Chemical data

Formula C35H36ClNO3S
Mol. mass 586.184 g/mol
SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability 63% to 73%
Protein binding 99%
Metabolism Hepatic (CYP3A4 and CYP2C9-mediated)
Half life 2.7-5.5 hours
Excretion Biliary

Before taking montelukast, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies.

Before using this drug, tell your doctor or pharmacist your medical history, especially of: liver disease.

Use of this medication is not recommended in children less than 15 years old.

This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

It is not known whether this drug is excreted into breast milk. Consult your doctor before breast-feeding.

SIDE EFFECTS

Side effects cannot be anticipated. If any develop or change in intensity, tell your doctor as soon as possible. Only your doctor can determine if it is safe for you to continue taking Montelukast sodium.

Side effects may include: abdominal pain, abnormal dreams, allergic reaction, bronchitis, bruising, cough, dental pain, depression, diarrhea, difficulty breathing or swallowing, dizziness, drowsiness, ear infection, ear pain, eczema, eye inflammation, fatigue, feeling anxious, fever, flu, hallucinations, headache, hives, indigestion and other digestive problems, infection, insomnia, irritability, itching, joint pain, laryngitis, leg pain, muscle aches and cramps, nasal congestion, nausea, pancreatitis, pins and needles/numbness, pneumonia, rash, restlessness, runny nose, seizures,

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sinus pain, skin inflammation, sneezing, sore throat, suicidal thoughts and actions (including suicide), swelling due to fluid retention, swelling of the mouth or throat, upper respiratory infection, tendency to bleed easily, thirst, tremor, viral infection, vomiting

DOSAGE

The information below is based on the dosage guidelines your doctor uses. Depending on your condition and medical history, your doctor may prescribe a different regimen. Do not change the dosage or stop taking your medication without your doctor's approval.

Asthma

Adults and children ≥15 years: The usual dose is one 10 milligram (mg) tablet once a day in the evening.
Children 6 to 14 years: The usual dose is one 5 mg chewable tablet once a day in the evening.
Children 2 to 5 years: The dosage is one 4 mg chewable tablet or 1 packet of 4 mg oral granules per day, taken in the evening.
Children 12 to 23 months: The dosage is 1 packet of 4 mg oral granules taken once a day in the evening.
The safety and effectiveness of Singulair for treating asthma in children <12 months have not been studied.
Seasonal Allergies in Adults and Children >2 years and Perennial (year-round) Allergies in Adults and Children ≥6 months
Adults and children >15 years: The usual dose is one 10 mg tablet once a day taken at any time.
Children 6 to 14 years: The usual dose is one 5 mg chewable tablet once a day taken at any time.
Children 2 to 5 years: The dosage is one 4 mg chewable tablet or 1 packet of 4 mg oral granules per day, taken at any time.
Children 6 to 23 months: The dosage is 1 packet of 4 mg oral granules per day, taken at any time.

DRUG DESCRIPTION

Singulair is a medicine called a leukotriene receptor antagonist. It works by blocking substances in the body called leukotrienes. Blocking leukotrienes improves asthma and allergic rhinitis.

Singulair is prescribed for the treatment of asthma, the prevention of exercise-induced asthma, and allergic rhinitis (sneezing, stuffy nose, runny nose, itching of the nose, and outdoor and indoor allergies).

Montelukast sodium, the active ingredient in , is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor.

Montelukast sodium is described chemically as [R -(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1 methylethyl)phenyl]propyl]thio]methyl]cyclopropaneacetic acid, monosodium salt.

The empirical formula is C35H35ClNNaO3S, and its molecular weight is 608.18.
Montelukast sodium is a hygroscopic, optically active, white to off-white powder. Montelukast sodium is freely soluble in ethanol, methanol, and water and practically insoluble in acetonitrile.

Each 10-mg film-coated tablet contains 10.4 mg montelukast sodium, which is equivalent to 10 mg of montelukast, and the following inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The film coating consists of: hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, red ferric oxide, yellow ferric oxide, and carnauba wax.

Each 4-mg and 5-mg chewable tablet contains 4.2 and 5.2 mg montelukast sodium, respectively, which are equivalent to 4 and 5 mg of montelukast, respectively. Both chewable tablets contain the following inactive ingredients: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, red ferric oxide, croscarmellose sodium, cherry flavor, aspartame, and magnesium stearate.

Each packet of 4-mg oral granules contains 4.2 mg montelukast sodium, which is equivalent to 4 mg of montelukast.

The oral granule formulation contains the following inactive ingredients: mannitol, hydroxypropyl cellulose, and magnesium stearate.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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