Taj Pharmaceuticals Ltd.

Desloratadine

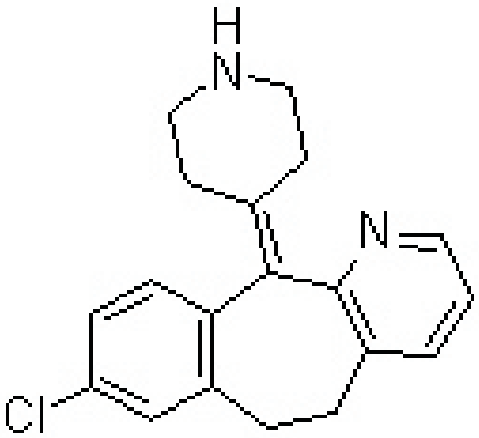
CAS No. : 100643-71-8

Synonyms

8-Chloro-6,11-dihydro-11-(4-piperdinylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine

Molecular Structure

Desloratadine Molecular Formula C19H19ClN2
Molecular Formula C19H19ClN2
Molecular Weight 310.82
CAS Registry Number 100643-71-8
ATC code R06AX27
PubChem 124087
DrugBank APRD00324



Chemical data

Formula C19H19ClN2
Mol. mass 310.82
SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability Rapidly absorbed
Protein binding 85%
Metabolism Liver
Half life 27 hours
Excretion 40% as conjugated metabolites into urine
Similar amount into the feces
Therapeutic considerations
Licence data
EU EMEA:link, US FDA:link
Pregnancy cat.
B1(AU) C(US)
Legal status
POM(UK) ℞-only(US)
Routes oral

DOSAGE

The recommended dose for adults and children 12 years or older is 5 mg daily. Syrup can be used for children two years and older with the dose dependent on the age of the child. Desloratadine can be taken with or without food.

Take this medication by mouth once a day or as directed by your doctor. Do not increase your dose or take this more often than directed. Do not take this medication for several days before allergy testing since test results may be affected.

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SIDE EFFECTS

This medication may cause throat discomfort, muscle pain, nausea, dizziness, fatigue, indigestion, or dry mouth. If these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if this unlikely but serious side effect occurs: rapid or pounding heartbeat. Desloratadine does not usually cause drowsiness when used at recommended doses and under normal circumstances. However, be sure of the drug's effects before engaging in activities that require alertness such as driving or using machinery. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking desloratadine, tell your doctor or pharmacist if you are allergic to it; or to loratadine; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease. Limit alcohol intake, as it may intensify drug side effects. Desloratadine should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Breast-feeding is not recommended while using this drug.

The carcinogenic potential of desloratadine was assessed using loratadine studies. In an 18-month study in mice and a 2-year study in rats, loratadine was administered in the diet at doses up to 40 mg/kg/day in mice (estimated desloratadine and desloratadine metabolite exposures were approximately 3 times the AUC in humans at the recommended daily oral dose) and 25 mg/kg/day in rats (estimated desloratadine and desloratadine metabolite exposures were approximately 30 times the AUC in humans at the recommended daily oral dose). Male mice given 40 mg/kg/day loratadine had a significantly higher incidence of hepato-cellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg/day and in males and females given 25 mg/kg/day. The estimated desloratadine and desloratadine metabolite exposures of rats given 10 mg/kg of loratadine were approximately 7 times the AUC in humans at the recommended daily oral dose. The clinical significance of these findings during long-term use of desloratadine is not known. In genotoxicity studies with desloratadine, there was no evidence of genotoxic potential in a reverse mutation assay (Salmonella/E. coli mammalian microsome bacterial mutagenicity assay) or in two assays for chromosomal aberrations (human peripheral blood lymphocyte clastogenicity assay and mouse bone marrow micronucleus assay).

There was no effect on female fertility in rats at desloratadine doses up to 24 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 130 times the AUC in humans at the recommended daily oral dose). A male specific decrease in fertility, demonstrated by reduced female conception rates, decreased sperm numbers and motility, and histopathologic testicular changes, occurred at an oral desloratadine dose of 12 mg/kg in rats (estimated desloratadine exposures were approximately 45 times the AUC in humans at the recommended daily oral dose). Desloratadine had no effect on fertility in rats at an oral dose of 3 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 8 times the AUC in humans at the recommended daily oral dose).

DRUG DESCRIPTION

Desloratadine is an oral, long-acting antihistamine that is similar chemically to loratadine (Claritin). It is used to treat the symptoms caused by histamine. Histamine is a chemical that is responsible for many of the signs and symptoms of allergic reactions, for example, swelling of the lining of the nose, sneezing, and itchy eyes. Histamine is released from histamine-storing cells (mast cells) and then attaches to other cells that have receptors for histamine. The attachment of the histamine to the receptors causes the cell to be "activated," releasing other chemicals which produce the effects that we associate with allergy. Desloratadine blocks one type of receptor for histamine (the H1 receptor) and thus prevents activation of H1 receptor-containing cells by histamine. Desloratadine does not readily enter the brain from the blood and, therefore, causes less drowsiness (sedation). It is a member of a small family of non-sedating antihistamines which includes loratadine (Claritin), cetirizine (Zyrtec), and azelastine (Astelin).

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture 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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This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009