Taj Pharmaceuticals Ltd.

Fexofenadine Hcl

CAS No. : 153439-40-8

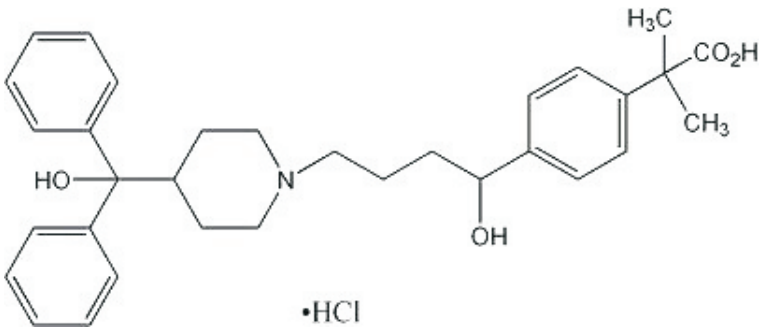
Systematic (IUPAC) name

2-[4-[1-hydroxy-4-[4-(hydroxy-diphenyl-

methyl)-1-piperidyl]butyl]phenyl]-2- methyl-propanoic acid

Identifiers

CAS number 153439-40-8
ATC code R06A626
PubChem 3348
DrugBank APRD00349
ChemSpider 3231



Chemical data

Formula C32H39NO4
Mol. mass 501.656
SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability Not yet established
Protein binding 60-70%
Metabolism Hepatic (5% of dose)
Half life 14.4 hours
Excretion Biliary , fecal and renal

USES

Fexofenadine is an antihistamine that provides relief of seasonal allergy symptoms such as runny or itchy nose, sneezing, itchy throat, and watery, itchy, or red eyes. It is also used for hives.

HOW TO USE

Take fexofenadine by mouth usually twice a day or as directed by your doctor. If you are taking the suspension, shake the bottle well before use. Take the regular tablet or suspension form of this medication with or without food. If you are using the rapidly dissolving tablet, take it on an empty stomach. Remove the rapidly dissolving tablet from its foil pack immediately before taking and place the tablet on the tongue. It will dissolve quickly. You may swallow the dissolved medication with or without water.

Taking fexofenadine with apple, grapefruit, or orange juice may decrease the absorption of this drug. Try to avoid taking fexofenadine with these types of fruit juices. If possible, take this drug with water instead.

Antacids containing aluminum and magnesium can decrease the absorption of this drug. Do not take antacids within 2 hours of taking this medication.
Do not increase your dose or take this more often than directed. Dosage is based on your medical condition (e.g., kidney disease) and response to treatment. In children, dosage is also based on age.

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SIDE EFFECTS

Stomach upset, menstrual cramps, back pain, cough, fever, stuffy nose, earache or dizziness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

This medication does not usually cause drowsiness when used at recommended doses and under normal circumstances. However, this drug may make you dizzy; therefore use caution engaging in activities that require alertness such as driving or using machinery.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

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.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

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

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

Limit alcoholic beverages, as it may intensify drug side effects. (See also Side Effects.)

The rapidly dissolving tablet may contain aspartame. If you have phenylketonuria (PKU) or any other condition that requires you to restrict your intake of aspartame (or phenylalanine), consult your doctor or pharmacist about using this drug safely.
Kidney function declines as you grow older. This medication is removed by the kidneys. The elderly may be more sensitive to the effects of this drug.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

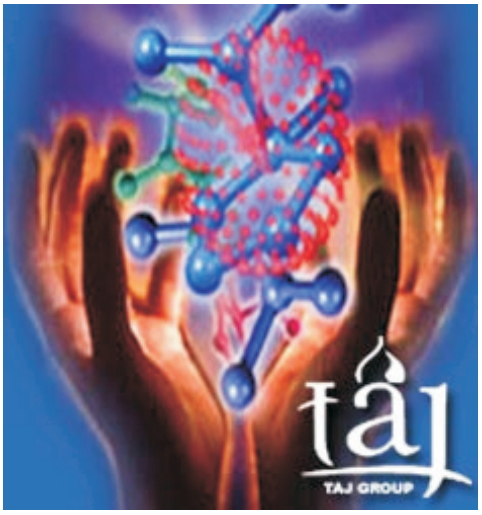
DOSAGE

For seasonal allergies the recommended dose for adults and children 12 years or older is 60 mg twice daily or 180 mg once daily. Children 6-11 years of age should be given 30 mg twice daily. For chronic urticaria, adults and children 12 years or older should use 60 mg twice daily, and children 6-11 years of age should use 30 mg twice daily. Fexofenadine can be taken with or without food.

Take Fexofenadine HCl on an empty stomach with water. You can take regular Fexofenadine HCl with or without food. Fexofenadine HCl must be swallowed whole; do not chew or crush the tablet.

If you miss a dose...
Take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular schedule. Do not take 2 doses at once

DRUG DESCRIPTION



Fexofenadine hydrochloride, the active ingredientandoral suspension, is a histamine H1-receptor antagonist with the chemical name (±)-4-[1 nylmethyl)-1-piperidinyl]-butyl]- a, a-dimethylhydroxy-4-benzeneacetic acid hydrochloride.

The molecular weight is 538.13 and the empirical formula is C32H39NO4•HCl.

Fexofenadine hydrochloride is a white to off-white crystalline powder. It is freely soluble in methanol and ethanol, slightly soluble in chloroform and water, and insoluble in hexane. Fexofenadine hydrochloride is a racemate and exists as a zwitterion in aqueous media at physiological pH.

Fexofenadine HCl is formulated as a tablet for oral administration. Each tablet contains 30, 60, or 180 mg fexofenadine hydrochloride (depending on the dosage strength) and the following excipients: croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The aqueous tablet film coating is made from hypromellose, iron oxide blends, polyethylene glycol, povidone, silicone dioxide, and titanium dioxide.

Fexofenadine HCl ODT is formulated for disintegration in the mouth immediately following administration. Each orally disintegrating tablet contains 30 mg fexofenadine hydrochloride and the following excipients: citric acid anhydrous, crospovidone, magnesium stearate, mannitol, methacrylate copolymer, microcrystalline cellulose, povidone K-30, sodium bicarbonate, sodium starch glycolate, aspartame, natural and artificial orange flavor, artificial cream flavor, and alcohol anhydrous; the alcohol is predominantly
removed during the

manufacturing process.

Fexofenadine HCl oral suspension, a white uniform suspension, contains 6 mg fexofenadine hydrochloride per mL and the following excipients: propylene glycol, edetate disodium, propylparaben, butylparaben, xanthan gum, poloxamer 407, titanium dioxide, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, artificial raspberry cream flavor, sucrose, xylitol and purified water.

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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