

AlergixTM MR

Mizolastine



Presentation

AlergixTM MR tablet: Each Modified Release Tablet contains Mizolastine INN 10 mg.

Description

Mizolastine is a second generation non-sedating antihistamine agent. It possesses antihistamine and antiallergic properties due to a specific and selective antagonism of peripheral histamine H₁ receptors. It has also been shown to inhibit histamine release from mast cells and the migration of neutrophils.

Indications and Uses

Mizolastine is used to reduce the symptoms of:

- Hay fever (seasonal allergic rhinoconjunctivitis)
- Allergic reactions causing irritation of the eyes and nose (perennial allergic rhinoconjunctivitis)
- Urticaria (an itchy skin rash, like nettle rash).

Dosage and Administration

Adults and children aged 12 years and over: the usual dose is one tablet (10 mg) daily.

The tablets should be taken with plenty of water. Do not take a double dose to make up for a forgotten tablet. If the treatment is discontinued before finishing the course of treatment, the physician should be informed.

To maintain modified release pattern, tablet should not be chewed or crushed.

Use in pregnancy & Lactation

The safety of Mizolastine in human pregnancy has not been established. As with all medicines, Mizolastine should be avoided in pregnancy, particularly during the first three months.

Mizolastine passes into breast milk, therefore Mizolastine should not be used during breast-feeding.

Contraindications

Mizolastine is contraindicated in allergy to mizolastine or any of the other ingredients of this medicine or patient taking macrolide antibiotics, imidazole antifungal medicines or having liver problems, heart problems, ever had an irregular heart beat or a slow heart rate, having an abnormal ECG (electrical recording of your heart beat) or already taking medicines for an irregular heart beat or having abnormal levels of salts in the blood, in particular low potassium levels.

Precautions

Sleepiness may be felt after taking this medicine. If this happens, do not drive or use any tools or machines. The elderly may be particularly susceptible to the sedative effects of mizolastine and the potential effects of the medicinal product on cardiac repolarisation.

Side effects

Mizolastine is well tolerated in the recommended doses. Doctor should be informed immediately and treatment should be stopped if patient experience dizziness, swelling of the face, lips, tongue or throat and difficulty in breathing, as these may be signs of a serious allergic reaction.

Common side effects includes dry mouth, headache, dizziness, drowsiness, lack of energy, diarrhoea, nausea, stomach pain, indigestion and increased appetite associated with weight gain.

Uncommon side effects includes anxiety and depression changes in blood tests which show how the liver is working, low blood pressure, fast or irregular heart rate and joint and muscle pains.

Drug Interaction

Although the bioavailability of mizolastine is high and the medicinal product is principally metabolized by glucuronidation, systemically administered ketoconazole and erythromycin moderately increase the plasma concentration of mizolastine and their concurrent use is contraindicated.

Concurrent use of other potent inhibitors or substrates of hepatic oxidation (cytochrome P450 3A4) with mizolastine should be approached with caution. These would include cimetidine, ciclosporin, and nifedipine.

Alcohol: In studies with mizolastine, no potentiation of the sedation and the alteration in performance caused by alcohol has been observed.

Overdose

In cases of overdose, general symptomatic surveillance with cardiac monitoring including QT interval and cardiac rhythm for at least 24 hours is recommended, along with standard measures to remove any unabsorbed medicinal product. Studies in patients with renal insufficiency suggest that haemodialysis does not increase clearance of the medicinal product.

Storage

Do not store above 30°C. Keep away from light and out of the reach of children.

Commercial Pack

AlergixTM MR tablet: Each box contains 3 blister strips of 10 Modified Release Tablets.