Rhinor® MR

Mizolastine

Description
Rhinor® MR is the preparation of Mizolastine. It possesses antihistamine and antiallergic properties due to specific and selective antagonism of peripheral histamine H_1 receptor.

Mode of action
Mizolastine works by blocking histamine H_1 receptor.

Composition
Rhinor® MR 10 mg Tablet: Each film coated modified release tablet contains Mizolastine INN 10 mg.

Indications
Rhinor® MR indicated for the symptomatic relief of the following conditions:
- Seasonal allergic rhinoconjunctivitis (hay fever)
- Perennial allergic rhinoconjunctivitis
- Urticaria

Dosage & administration
Adult and children above 12 years: The usual recommended dose is one 10 mg tablet daily.
Children below 12 years: Not recommended.

Contraindications
Mizolastine is contra-indicated in patients with clinically significant cardiac disease or a history of symptomatic arrhythmias and in patients with known or suspected QT prolongation, patients with electrolyte imbalance (particularly hypokalaemia), and in those with clinically significant bradycardia. It is also contra-indicated in patients taking other drugs that decrease its metabolism, patients with significantly impaired liver function, and in patients who are hypersensitive to the drug.

Side effects
Mizolastine is well tolerated in the recommended doses. The usual side effects are dry mouth, diarrhea, abdominal pain, nausea, drowsiness, headache, dizziness, raised liver enzymes, hypotension, tachycardia and palpitations. Bronchospasm and aggravation of asthma were reported, but in view of the high frequency of asthma in the treated patient population, a causality relationship remains uncertain.

Use in pregnancy & lactation
The safety of Mizolastine for use in human pregnancy has not been established. The evaluation of experimental animal studies does not indicate direct or indirect harmful effects with respect to the development of the embryo or fetus, the course of gestation and peri and post-natal development. Mizolastine should be avoided in pregnancy (particularly the 1st trimester). Mizolastine is excreted into breast milk, therefore it is not recommended during lactation.

Precautions
Patients should be warned that a small number of individuals may experience sedation; it is therefore advisable to determine individual response before driving or performing complicated task.

Drug interactions
Systemically administered Ketoconazole and Erythromycin, antiarrythmics e.g. Amiodarone moderately increase the plasma concentration of Mizolastine. This could increase the risk of arrhythmias. Concurrent use of other potent inhibitor of the cytochrome P450 3A4 enzyme e.g. Cyclosporine should be approached with caution. No potentiation of the sedation and the alteration in performance caused by alcohol with Mizolastine has been observed.

Over dosage
In cases of over dosage, 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 drug. Studies in patients with renal insufficiency suggest that haemodialysis does not increase clearance of the drug.

Storage
Store in a cool and dry place, protected from light.

Packaging
Rhinor® MR 10 mg Tablet: Each Carton contains 10X5 tablets in blister pack.

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Opsonin Pharma
Ideas for healthcare

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