Mastel®

Mizolastine

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

Indications
Mastel ® is indicated for the symptomatic relief of the following conditions:

- Seasonal allergic rhinoconjunctivitis (hay fever)
- Perennial allergic rhinoconjunctivitis
- Urticaria

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

Pregnancy and 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 foetus, 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.

Side effects
Mizolastine is well tolerated in the recommended doses. The usual side effects are dry mouth, diarrhoea, 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.

Contra-indications
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.

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 arrythmias. Concurrent use of other potent inhibitor of the cytochrome P_{450} 3A4 enzyme e.g. Ciclosporin should be approached with caution. No potentiation of the sedation and the alteration in performance caused by alcohol with Mizolastine has been observed.

Overdosage
In cases of overdosage, 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.

Pharmaceutical Precaution
Store in a cool & dry place. Protect from light. It should be kept out of the reach of children.

Presentation
Mastel ® 10mg tablet: White, round, modified release tablet. Each modified release tablet contains Mizolastine INN 10mg.

Packing Quantities
Mastel ® 10mg tablets: Carton of 3X10's tablet in Alu-PVC blister.

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ACI Limited
Narayanganj, Bangladesh

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