Only for the use of Medical Professionals

Largix®

Rupatadine

Description

Largix® is a preparation of Rupatadine Fumarate which is a second generation non-sedating, selective and long-acting histamine H1 receptors and platelet-activating factor (PAF) antagonist. Rupatadine has dual mechanism. Both histamine and PAF cause bronchoconstriction which leads to an increase in the vascular permeability and act as a mediator in the inflammatory process. With the dual mode of action, **Largix**® shows better therapeutic effect than an isolated antihistamine. It also suppresses the release of several inflammatory mediators in response to allergens by inhibiting the degranulation of mast cells, and reducing the release of cytokines including tumour necrosis factor (TNFα) from mast cells and monocytes.

Indications

Largix® is indicated for symptomatic treatment of seasonal & perennial allergic rhinitis and urticaria.

Dosage & administration

Adults and adolescents (above 12 years)

Largix® **Tablet**: 10 mg (one tablet) once daily.

Children age 2-11 years

Largix® **Syrup**

• Children weighing equal or more than 10 kg to less than 25 kg: 1/2 teaspoonful (2.5 ml) of syrup once a day with or without food.
• Children weighing 25 kg or more: 1 teaspoonful (5 ml) of syrup once a day with or without food.

Children less than 2 years

The use of Rupatadine below the age of 2 years is not recommended.

Patients with renal and hepatic insufficiency

The use of Rupatadine in patient with renal and hepatic insufficiency is not recommended.

Use in pregnancy and lactation

Pregnancy

Rupatadine is pregnancy category B2. Available limited data showed no adverse effect of Rupatadine on pregnancy or the fetus or newborn child. Since data are not sufficient, pregnant women should use Rupatadine if the expected benefits outweigh the potential risk to the mother and child.

Lactation

No information is available, whether Rupatadine is excreted in the mother's milk. Therefore, it should be used during lactation if the potential benefits outweigh the potential risk to the mother and child.

Side effects

The most common side effects of Rupatadine are sleepiness, headache, dizziness, dry mouth, sensation of weakness and fatigue.

Contraindications

Rupatadine is contraindicated in patients with known hypersensitivity to Rupatadine or to any of the components of this product.

Precautions

Rupatadine should be used with caution in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, patients with bradycardia, acute myocardial ischemia. It should also be used with caution in elderly patients (aged over 65 years).

Drug interactions

The concomitant administration of Rupatadine and Ketoconazole or Erythromycin increase the systemic exposure, Rupatadine should be used with caution when it is administered concomitantly with these drug substance and other inhibitors of the isozyme CYP3A4 may decrease the metabolism of Rupatadine. Rupatadine should be used with caution when it is co-administered with statins or CNS depressants or alcohol.

Overdose

If accidental ingestion of very high doses occurs, then symptomatic treatment should be given together with the required supportive measures.

Pharmaceutical precautions

Keep away from the reach of children.
Largix® Tablet: Store in a cool (below 25oC) & dry place protected from light.
Largix® Syrup: Store in a cool & dry place protected from light.

Presentation

Largix® Tablet: Each coated tablet contains Rupatadine 10 mg as Fumarate INN.
Largix® Syrup: Each 5 ml contains Rupatadine 5 mg as Fumarate INN.

Package quantities

Largix® Tablet: Carton of 30 tablets in blister pack.
Largix® Syrup: Bottle of 60 ml.

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