RHINITIN TABLET 10mg
RHINITIN SYRUP 5mg/5ml

Description:
Each Rhinitin Tablet contains 10mg Loratadine. A white to off white oblong shaped tablet with score on one side
Each 5ml Rhinitin Syrup contains 5mg Loratadine. A clear syrup having fruity flavour

Actions & Pharmacology: Loratadine is a long-acting tricyclic antihistamine with potent, selective antagonistic activity on peripheral H1-receptors. It acts by competing for H1-receptor sites on effector cells, thereby preventing, but not reversing, actions mediated by histamine alone. Loratadine does not readily cross the blood-brain barrier and CNS depression is not significant. Loratadine is well-absorbed after oral administration. Ingestion of food may enhance absorption by 40%. It is metabolized in the liver to descarbethoxyloratadine which is an active metabolite. Peak plasma concentration of loratadine is reached after 1 to 2 hours while that of the active metabolite is reached at 3 to 4 hours. Peak effects are observed after 4 to 6 hours. Duration of action of loratadine is at least 24 hours.
Loratadine is about 97% protein-bound, while its active metabolite is about 75% protein-bound. Approximately 80% of the total dose administered is excreted equally in urine and faeces as metabolites after 10 days.
Loratadine is distributed into breast milk, reaching concentrations equivalent to that in plasma.

Indications: Rhinitin Tablet and Syrup are indicated for relief of symptoms associated with allergic rhinitis as well as ocular itching and burning, chronic urticaria and other allergic dermatologic disorders

Dosage & Administration:
Adults & children ≥ 12 years old: Take one tablet daily
Children 2-12 years, body weight >30kg: Take two 5ml spoonfuls syrup (10mg) daily;
Body weight ≤ 30kg: Take one 5ml spoonful syrup (5mg) daily.

Route of administration:
Oral administration

Contraindications: Contraindicated in patients who are hypersensitive to loratadine or any other components in Rhinitin Tablet or Syrup

Precautions: Dosage adjustment is required in patients who have severely impaired hepatic function due to possibility of reduced clearance of loratadine. Such patients should be administered a lower initial dose, at 5mg daily, or 10mg every other day.
Use in children: Safety and efficacy of loratadine in children below two years old have not been established.
Use in elderly patients: Elderly patients are more likely to have age-related renal function impairment and hence may be more likely to experience adverse effects due to accumulation of the drug.
Use in pregnant and lactating mothers: Safety of loratadine during pregnancy has not been established. Loratadine should be used only when potential benefits outweigh the potential risk to the fetus. Loratadine is excreted into breast milk. Considering the greater sensitivity of infants to antihistamines, a decision should be made whether to discontinue breastfeeding while being treated with loratadine, or to discontinue the drug.

Drug interactions: Studies did not show any potentiating effects of loratadine with alcohol. When used concurrently with ketoconazole, erythromycin or cimetidine, plasma concentrations of loratadine may be increased. Other drugs known to inhibit hepatic metabolism should be co-administered with caution.

As with other antihistamines, loratadine should be stopped approximately 48 hours prior to skin testing since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity indicators.

Adverse effects: Loratadine does not have any clinically significant sedative or anticholinergic effects at the usual recommended dose of 10mg. Incidence of the most commonly reported side-effects during clinical trials of loratadine, including dry mouth, nausea, gastritis, fatigue, sedation, headache and skin rash, were comparable to that of placebo. Alopecia, anaphylaxis and disturbances in liver function have been reported rarely. Similarly, the incidence of treatment related side-effects in paediatric patients, such as headache, sedation and nervousness, were rare and comparable to that of placebo.

Overdosage & **Treatment:** Sedation, tachycardia and headache have been reported in cases of overdosage. A single acute ingestion of 160mg did not produce any significant adverse effects.
Treatment of overdosage should be supportive and symptomatic.
Patient should be induced to vomit, such as by the administration of ipecac syrup together with 240ml to 360ml of water. After emesis, administer activated charcoal as a slurry in water to adsorb any drugs remaining in the stomach.
If vomiting is unsuccessful or contraindicated, gastric lavage should be performed, preferably with physiological saline (especially in children), or tap water. Saline cathartics may help by drawing water into the bowel, hence rapidly diluting the bowel contents. Loratadine is not removed by haemodialysis.
After emergency treatment the patient should continue to be monitored for vital signs.

Storage:
Store in a dry place below 30°C
Protect from light.
Keep container tightly close
Keep out of the reach of children
Jauhkan dari kanak-kanak

Shelf-life:
Rhinitin Tablet: Blister: 4 years
Rhinitin Syrup: Bottles: 4 years

Presentation:
Rhinitin Tablet : Blister of 10 tablets, Box of 10 and 50 strips.
Rhinitin Syrup : Bottles 60, 90, 120ml.

Manufactured by:
Noripharma Sdn. Bhd., Lot 5030, Jalan Teratai, 5 1/2 Mile off Jalan Meru, 41050 Klang, Selangor.

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