

(Levocitrizen 5 mg + Montelukast 10mg)

Each Tablet Contains:

Levocetirizine Dihydrochloride IP	5 mg
Montelukast Sodium IP	. 10 mg
Excipientsq.s.	

Clinical Pharmacology:

Levocetirizine: Levocetirizine is an antihistamine that acts as a selective antagonist of the H1-receptor. It works by inhibiting the effects of histamine, a substance in the body that causes allergic symptoms. It reduces symptoms of allergic rhinitis, such as sneezing, runny nose, and itching, as well as symptoms of chronic urticaria (hives).

Montelukast: Montelukast is a leukotriene receptor antagonist that blocks the action of leukotrienes, substances in the body that are involved in the inflammation and constriction of airways. By blocking leukotrienes, Montelukast helps prevent asthma attacks and also relieves symptoms of allergic rhinitis.

Indications:

- Seasonal allergic rhinitis (hay fever).
- Perennial allergic rhinitis.
- Chronic urticaria (hives).
- Asthma prophylaxis.
- Relief of symptoms of allergic rhinitis associated with asthma.

Contraindications:

Hypersensitivity to Levocetirizine, Montelukast, or any of the excipients in the formulation. Severe renal impairment (creatinine clearance less than 10 mL/min) for Levocetirizine. - Patients with phenylketonuria due to the presence of aspartame (if applicable).

Precautions and Warnings:

• Somnolence: Levocetirizine may cause drowsiness; caution should be exercised when operating machinery or driving.

- Neuropsychiatric Events: Montelukast has been associated with neuropsychiatric events such as agitation, aggression, depression, and suicidal thoughts. Patients should be monitored for these symptoms.
- Renal Impairment: Use with caution in patients with moderate renal impairment. Liver Dysfunction: Montelukast should be used with caution in patients with liver dysfunction.

Drug Interactions:

- Levocetirizine: May interact with alcohol and CNS depressants, increasing the risk of drowsiness.
- Montelukast:May interact with inducers of the cytochrome P450 enzyme system, such as phenobarbital and rifampin, which can decrease its effectiveness.Adverse Effects:
 - Levocetirizine: Common adverse reactions include somnolence, fatigue, dry mouth, and headache.
 - Montelukast: Common adverse reactions include headache, abdominal pain, flulike symptoms, and increased liver enzymes.

Overdosage:

- Levocetirizine: Symptoms of overdose may include drowsiness in adults and agitation and restlessness followed by drowsiness in children. Symptomatic and supportive treatment is recommended.
- Montelukast: Symptoms of overdose may include abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity. Treatment is symptomatic and supportive.

Route of Administration:

Oral. Tablets should be swallowed whole with water. Not to be crushed or chewed.

SCHEDULE H PRESCRIPTION DRUG CAUTION:

Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Dosage:

As directed by the Physician.

Storage:

Store in a cool, dry place below 25°C. Protect from light and moisture.

Presentation:

Available as 1 x 10 Tablets/Strip.



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