

Patient Leaflet

Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP

AMERICAN Montelovo मॉटेलोवी Tablets

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

What This Combination Is used For

This combination is used to relieve and control:

- **Allergic rhinitis** (sneezing, runny or blocked nose, itchy/watery eyes)
- **Night-time allergy symptoms**
- **Asthma-related allergy symptoms** (Montelukast component only)

How the Medicines Work

- **Levocetirizine**: An antihistamine that reduces itching, sneezing, and runny nose.
- **Montelukast**: A leukotriene blocker that reduces inflammation, swelling, and narrowing of airways.
- Together, they help provide **better control of allergy symptoms**, especially at night.

HOW TO TAKE :

- Always take Levocetirizine and Montelukast exactly as your doctor has told you.
- You should check with your doctor or pharmacist if you are not sure.
- You should swallow the tablet whole with water or another liquid.
- The usual recommended daily dose is Adults (>15 years): 1 tablet once daily.
- If you suffer from mild to moderate kidney failure, your doctor may prescribe a lower dose according to the severity of your kidney disease. The duration of treatment depends on the type, duration and course of the complaints. Your doctor or pharmacist will advise you on this.

If you miss a dose:

Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet at the usual time.

Clinical Particulars:

Therapeutic indication Montelukast Sodium / Levocetirizine Dihydrochloride film coated tablets are indicated for chronic allergic conditions like seasonal allergic rhinitis, perennial allergic rhinitis, rhinitis associated with asthma.

Posology and method of administration Adults (> 15 years):

1 tablet once daily.

Use in Children:

The safety and effectiveness of Montelukast and Levocetirizine at 10 mg and 5 mg respectively in paediatric patients under 15 years of age have not been established.

Use in Elderly:

Montelukast: No overall differences in safety or effectiveness were

observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Common Side Effects

Levocetirizine may cause:

- Drowsiness or tiredness • Dry mouth • Headache **Montelukast may cause:**
- Headache • Stomach discomfort • Sore throat

Less Common but

Important Side Effects

Seek medical advice if these occur:

Montelukast (rare but serious):

- Mood or behavior changes
 - Sleep disturbances
 - Anxiety, irritability, depression
 - Allergic reactions (rash, swelling, breathing difficulty)
- ##### Levocetirizine (rare):
- Allergic reactions
 - Difficulty urinating

Precautions

- Avoid alcohol (may increase drowsiness from levocetirizine).
- Use with caution in people with **kidney problems** (due to levocetirizine).
- Inform your doctor if you have a **history of mental health issues** (montelukast).
- Safe use in pregnancy or breastfeeding should be confirmed with a doctor.

Pregnancy and lactation Montelukast:

Use during pregnancy Animal studies do not indicate harmful effects with respect to effects on pregnancy or embryonal/foetal development. Montelukast may be used during pregnancy only if it is considered to be clearly essential. Use during lactation Studies in rats have shown that montelukast is excreted in milk. It is not known if montelukast is excreted in human milk. Montelukast may be used in breast-feeding mothers only if it is considered to be clearly essential.

Effects on ability to drive and use machines Montelukast:

Montelukast is not expected to affect a patient's ability to drive a car or operate machinery. However, in very rare cases, individuals have reported drowsiness or dizziness.

Drug-Drug Interactions Checker List:

- DICLOFENAC • NAPROXEN • IBUPROFEN • FLUCONAZOLE
- MICONAZOLE • ASPIRIN • VORICONAZOLE

Storage : Store protected from light & moisture, at a temperature not exceeding 30°C.

Keep all medicine out of reach of children.

Marketed by:



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