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 IS IN THIS LEAFLET

- What ALLERCET M Tablets are and what they used for
- Before you take ALLERCET M
- How to take ALLERCET M
- Possible side effects
- How to store ALLERCET M
- Further information

1. WHAT ALLERCET M IS AND WHAT THEY USED FOR

Levocetirizine

Levocetirizine, the (R) enantiomer of cetirizine, is a potent and selective antagonist of peripheral H1-receptors. Binding studies revealed that Levocetirizine has high affinity for human H1-receptors (Ki = 3.2 nmol/l). Levocetirizine has an affinity 2-fold higher than that of cetirizine (Ki = 6.3 nmol/l). Levocetirizine dissociates from H1-receptors with a half-life of 115 ± 38 min. After single administration, Levocetirizine shows receptor occupancy of 90% at 4 hours and 57% at 24 hours.

Montelukast

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotriene. Leukotriene's cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotriene, Montelukast 10 mg film-coated tablets improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Montelukast and Levocetirizine Tablets are indicated for relief of symptoms of allergic rhinitis (seasonal and perennial).

2. BEFORE YOU TAKE ALLERCET M TABLETS

Do not take Levocetirizine Dihydrochloride 5 mg & Montelukast if

- You are allergic (hypersensitive) to Levocetirizine & Montelukast any other related substance or any of the other ingredients of Levocetirizine Dihydrochloride 5 mg & Montelukast (see section 6).
- you suffer from severe kidney failure (less than 10 ml/min creatinine clearance)
- you have been told by your doctor that you have an intolerance to some sugars

Talk to your doctor or pharmacist or nurse before taking Montelukast tablets

• If your asthma or breathing gets worse, tell your doctor immediately.

• Oral Montelukast 10 mg film-coated tablets are not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.

• It is important that you or your child take all asthma medications prescribed by your doctor. Montelukast tablets should not be substituted for other asthma medications your doctor has prescribed for you.

• Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.

Take special care with Levocetirizine Dihydrochloride 5 mg

- If you suffer from epilepsy or are in any other way at risk of suffering fits. You should ask your doctor for advice.
- If you suffer from kidney failure. You may require a lower dosage and should discuss your situation with your doctor.

Levocetirizine is not recommended in children less than 6 years since the currently available film-coated tablets do not allow dose adaptation.

Other medicines may be affected by Levocetirizine & Montelukast. They, in turn, may affect how well Levocetirizine & Montelukast works.

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Levocetirizine Dihydrochloride & Montelukast with food and drink

Levocetirizine may be taken with or without food.

You should be cautious if you take Levocetirizine & Montelukast at the same time as **alcohol** In sensitive patients the effect of alcohol may be increased or different than expected.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. HOW TO TAKE ALLERCET M TABLETS

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.

If have taken more than the recommended dosage

If you have taken more Levocetirizine & Montelukast than you should, you may experience the following symptoms: confusion, diarrhoea, dizziness, fatigue, headache, feeling unwell, dilation of the pupils, itching, restlessness, drowsiness, sleepiness, fast heart beat, shaking and difficulty passing urine. Contact your doctor or pharmacist immediately. They may empty your stomach or can take other measures to alleviate the symptoms.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You must tell your doctor right away if you get one or more of these symptoms. In clinical studies with Montelukast 10 mg film-coated tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to Montelukast 10 mg film-coated tablets were:

• Abdominal pain

• Headache

Like all medicines, Levocetirizine can cause side effects, although not everybody gets them.
Common side effects (occurring in more than 1 in 100 treated patients):

- Sleepiness
- Dizziness
- Headache
- Inflammation of the throat
- Swelling and irritation inside the nose (in children)
- Abdominal pain
- Dry mouth
- Feeling sick
- Tiredness

Uncommon side effects (occurring in more than 1 in 1000, but in less than 1 in 100 treated patients):

- Sensation of tingling or numbness of the skin
- Diarrhoea
- Rash
- Itching
- Feeling of weakness
- Feeling unwell
- Agitation

Rare side effects (occurring in more than 1 in 10,000 but in less than 1 in 1000 treated patients):

- Faster heart beat
- Fits
- Disorders of movement
- Hives
- Swelling of the skin
- Hypersensitivity (allergic reaction)
- Abnormal liver function

5. HOW TO STORE ALLERCET M TABLETS

Keep out of the reach and sight of children.
Do not use Levocetirizine & Montelukast after the expiry date which is stated on the packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year.
The expiry date refers to the last day of that month.
Store in the original package to protect from moisture
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Allercet M contains,

Active ingredient: Montelukast and Levocetirizine dihydrochloride
Inactive ingredient: Lactose, Prege. Starch, Cross Povidone Type-A (Polyplasdone-XL), Talc, Magnesium stearate, H.P.M.C 15 CPS, Titanium dioxide, Iron oxide yellow

What Allercet M looks like and contents of the pack,

Yellow, circular, biconvex film-coated tablets with MICRO/MICRO engraved on both sides
Blister pack of 10's

Manufacturer

MICRO LABS LIMITED

No. 92, Sipcot Industrial Complex
Hosur -635 126 (TN)
INDIA

Marketing Authorisation Holder

MICRO LABS LIMITED

31. Race Course Road
Bangalore-560001
INDIA

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