

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **BREATHEZY-L (10/5)**

**(Montelukast sodium 10 mg and Levocetirizine dihydrochloride 5 mg)**

**Read all of this 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.

#### **In this leaflet:**

1. What BREATHEZY- L is and what it is used for
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#### **1. What BREATHEZY- L is and what it is used for**

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes.

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms.

By blocking leukotrienes, Montelukast improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis). Your doctor has prescribed Montelukast to treat asthma, preventing your asthma symptoms during the day and night.

- Montelukast is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast is indicated in asthma, Montelukast can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast should be used depending on the symptoms and severity of your asthma.

What is asthma?

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of the airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

### **What are seasonal allergies?**

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

**Levocetirizine dihydrochloride** is also the active ingredient of BREATHEZY- L. BREATHEZY- L is an antiallergic medication.

For treatment of signs of illness (symptoms) associated with:

- allergic rhinitis (including persistent allergic rhinitis);
- nettle rash (urticaria).

### **2. Before you take BREATHEZY-L**

Do not take BREATHEZY- L

Tell your doctor about any medical problems or allergies you have now or have had.

Do not take BREATHEZY- L if you

- if you are allergic (hypersensitive) to Montelukast sodium and Levocetirizine dihydrochloride or to an antihistamine or any of the other ingredients of BREATHEZY- L (see 6. Further information).
- if you have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 ml/min).

### **Take special care with BREATHEZY-L**

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Breathezy-L is 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. Breathezy-L 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.
- You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.
- The use of Levocetirizine dihydrochloride is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

### **Taking other medicines**

Some medicines may affect how BREATHEZY- L works, or BREATHEZY- L may affect how other medicines work.

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

Tell your doctor if you are taking the following medicines before starting BREATHEZY- L:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)

### **Taking BREATHEZY-L with food and drink**

Montelukast 10 mg may be taken with or without food.

Caution is advised if Breathezy-L is taken at the same time as alcohol. In sensitive patients, the simultaneous use of cetirizine or levocetirizine and alcohol or other centrally acting agents may have effects on the central nervous system, although the racemate cetirizine has been shown not to increase the effect of alcohol.

### **Pregnancy and Breast-feeding**

#### *Use in pregnancy*

Women who are pregnant or intend to become pregnant should consult their doctor before taking

BREATHEZY-L. Your doctor will assess whether you can take BREATHEZY-L during this time.

#### *Use in breast-feeding*

It is not known if BREATHEZY-L appears in breast milk. You should consult your doctor before taking BREATHEZY-L if you are breast-feeding or intend to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are pregnant, trying to get pregnant or breast-feeding.

### **Driving and using machines**

Montelukast is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with Montelukast may affect some patients' ability to drive or operate machinery.

Some patients being treated with Levocetirizine Dihydrochloride may experience somnolence / drowsiness, tiredness and exhaustion. If you are intending to drive, engage in potentially hazardous activities or use machines you are therefore advised first to wait and observe your response to the medication. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking Levocetirizine Dihydrochloride in the recommended dosage.

### **Important information about some of the ingredients of BREATHEZY-L**

BREATHEZY-L film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take BREATHEZY- L**

- You should take only one tablet of BREATHEZY- L once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- Always take BREATHEZY- L as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- To be taken by mouth

#### **For adults 15 years of age and older:**

One tablet to be taken daily in the evening. BREATHEZY-L may be taken with or without food. If you are taking BREATHEZY-L, be sure that you do not take any other products that contain the same active ingredient, montelukast or cetirizine.

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease.

Patients who only have impaired liver function should take the usual prescribed dose.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Levoetirizine dihydrochloride is not recommended for children under 6 years of age.

Special dosage instructions for specific populations: **If you take more BREATHEZY-L than you should** Contact your doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

**If you forget to take BREATHEZY-L**

Try to take BREATHEZY-L as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking BREATHEZY-L**

BREATHEZY-L can treat your asthma only if you continue to take it.

It is important to continue taking SINGULAIR for as long as your doctor prescribes. It will help control your asthma.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Montelukast can cause side effects, although not everybody gets them.

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 were:

- abdominal pain
- headache

These were usually mild and occurred at a greater frequency in patients treated with SINGULAIR than placebo (a pill containing no medication).

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects at least 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

Additionally, while the medicine has been on the market, the following have been reported:

- upper respiratory infection (Very common)
- increased bleeding tendency (Rare)

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (Uncommon)
- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (Uncommon); tremor (Rare); hallucinations, disorientation, suicidal thoughts and actions (Very rare)]
- dizziness, drowsiness, pins and needles/numbness, seizure (Uncommon)
- palpitations (Rare)
- nosebleed (Uncommon)
- diarrhoea, nausea, vomiting (Common); dry mouth, indigestion (Uncommon)
- hepatitis (inflammation of the liver) (Very rare)
- rash (Common); bruising, itching, hives (Uncommon); tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning (Very rare)
- joint or muscle pain, muscle cramps (Uncommon)
- fever (Common); tiredness, feeling unwell, swelling (Uncommon)

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.

Ask your doctor or pharmacist for more information about side effects. 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.

Like all medicines, Levocetirizine dihydrochloride can cause side effects, although not everybody gets them. Commonly (1% to 10%), mainly mild to moderate side effects such as dry mouth, headache, tiredness and somnolence/drowsiness have been reported. Uncommon (0.1% to 1%), side effects such as exhaustion and abdominal pain have been observed. Other side effects such as palpitations, increased heart rate, convulsions, visual disturbances, oedema, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption, shortness of breath, weight increase, muscular pain, aggressive or agitated behaviour, hallucination, depression, hepatitis, abnormal liver function, nausea and vomiting have also been reported. At the first signs of a hypersensitivity reaction, stop taking Breathezy-L and see your doctor immediately. Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties together with hives (angioedema), sudden fall in blood pressure leading to collapse or shock, which may be fatal.

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.

## **5. How to store BREATHEZY-L**

- Keep out of the reach and sight of children.
- Do not use this medicine after the date the EXP date on the blister.

This medicine expires at the end of the month shown.

- Store in the original package in order to protect from light and moisture.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Further information**

### **What BREATHEZY-L contains**

The active substances of BREATHEZY-L film-coated tablets is Montelukast sodium and Levocetirizine dihydrochloride. Each tablet contains Montelukast sodium Ph.Eur wquivalent to Montelukast 10 mg and Levocetirizine dihydrochloride 5 mg.

Montelukast 10 mg and Levocetirizine dihydrochloride 5 mg film-coated tablets also contain the following inactive ingredients: Lactose monohydrate, Microcrystalline cellulose pH 112, Croscarmellose sodium, Hydroxy propyl cellulose, Magnesium stearate, Yellow oxide of iron, Colloidal silicon dioxide, Instacoat aqua IC-A-329, Purified water.

### **What Eppone looks like and contents of the pack**

The BREATHEZY-L tablet is a Round shaped, film coated, bi layered tablets, one layer with yellow color and another layer with white to off-white color having plain surface on both sides.

BREATHEZY- L film-coated tablets are available in Aluminium-Aluminium blister pack containing 10 tablets.

### **Marketing Authorization Holder and Manufacturer**

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