

PATIENT INFORMATION LEAFLET (PIL)

ODIMONT L

(Montelukast and Levocetirizine Dihydrochloride Tablets 10mg/5mg)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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:

1. What ODIMONT L is and what it is used for
2. Before you take ODIMONT L
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4. Possible side effects
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1. What ODIMONT 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 ODIMONT L which is an antiallergic medication.

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

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

2. Before you take ODIMONT L

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

Do not take ODIMONT L

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

Warnings and precautions

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast 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. Montelukast 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.
- If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.
- If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of Levocetirizine dihydrochloride may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking Levocetirizine dihydrochloride for several days before testing. This medicine may affect your allergy test results.

Children

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.

Do not give this medicine to children less than 15 years of age.

Taking other medicines

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 ODIMONT L:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for treatment of high lipid levels in plasma)

Taking ODIMONT L with food and drink

ODIMONT L mg may be taken with or without food.

Caution is advised if Levocetirizine dihydrochloride is taken at the same time as alcohol or other agents acting on the brain.

In sensitive patients, the concurrent administration of Levocetirizine dihydrochloride and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking ODIMONT L.

Pregnancy

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

Breast-feeding

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

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. Use caution when driving or operating machinery until you know how this medicine affects you. 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 in the recommended dosage.

Important information about some of the ingredients of ODIMONT L

These 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 ODIMONT L

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- You should take only one tablet of ODIMONT 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.
- To be taken by mouth

For adults 15 years of age and older:

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

Special dosage instructions for specific populations:

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

Patients who have severe impairment of kidney function must not take this medicine.

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.

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

If you take more ODIMONT 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 ODIMONT L

Try to take ODIMONT 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 ODIMONT L

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

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

Rarely pruritus (intense itching) may occur if you stop taking ODIMONT L, even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously.

In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

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 ((may affect up to 1 in 10 people) thought to be related to Montelukast were:

- abdominal pain
- headache

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

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment.

Uncommon: the following may affect up to 1 in 100 people

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure

Rare: the following may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: the following may affect up to 1 in 10,000 people

- 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)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

Other side effects

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: the following may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon: the following may affect up to 1 in 100 people

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare: the following may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following may affect up to 1 in 10,000 people

- tender red lumps under the skin, most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

Like all medicines, **Levocetirizine dihydrochloride** can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon: may affect up to 1 in 100 people

Exhaustion and abdominal pain

Not known: frequency cannot be estimated from the available data

Other side effects such as palpitations, increased heart rate, fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement, visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements), painful or difficult urination, inability to completely empty the bladder, oedema, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption, shortness of breath, weight increase, muscular pain, joint pain, aggressive or agitated behaviour, hallucination,

depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmare, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea have also been reported. Pruritus (intense itching) upon discontinuation.

At the first signs of a hypersensitivity reaction, stop taking this medicine and tell your doctor. Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/ or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden fall in blood pressure leading to collapse or shock, which may be fatal.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via email us at drugsafety@zyduslife.com or visit www.zyduslife.com

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ODIMONT L

Store upto 30°C. Keep out of reach of children.

Do not use this medicine after the expiry date, which is stated on the blister or carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Further information

What **ODIMONT L** Tablets contains

- The active substance is Montelukast Sodium equivalent to Montelukast and Levocetirizine Dihydrochloride.
- Each ODIMONT L tablet contains Montelukast Sodium equivalent to 10 mg Montelukast and 5 mg Levocetirizine Dihydrochloride.
- The other ingredients are Microcrystalline Cellulose, Lactose Monohydrate, Croscarmellose Sodium, Hydroxypropyl Cellulose, Magnesium Stearate, Opadry Yellow 20A82772 (Hypromellose, Hydroxypropyl Cellulose, Titanium Dioxide, Iron Oxide Yellow & Iron Oxide Red)

What **ODIMONT L** looks like and contents of the pack

ODIMONT L tablet is a Light yellow to yellow colored, round shaped, beveled edge, biconvex, film coated tablets, debossed with 'ML' on one side and plain on other sides. The tablets should be free of all physical defects.

ODIMONT L tablet is available in blister pack of 10 tablets.

Marketing Authorisation Holder and Manufacturer

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