

PACKAGE LEAFLET: INFORMATION FOR THE USER

Montelukast 10 mg Film-Coated Tablets Montelukast

For adolescents from 15 years and older and adults

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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Montelukast 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 and helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Your doctor has prescribed this medicine to treat your 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 patients from 15 years of age and older.
- In those asthmatic patients in whom Montelukast is indicated in asthma, this medicine can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how this medicine 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.

2. What you need to know before you take Montelukast

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

Do not take Montelukast

- if you are allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Montelukast

- If your asthma or breathing gets worse, tell your doctor immediately.
- This medicine 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 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 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.

Children and adolescents

For children 2 to 5 years old, montelukast as 4 mg chewable tablets and 4 mg granules are available. For children 6 to 14 years old, montelukast as 5 mg chewable tablets are available.

Other medicines and Montelukast

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how montelukast works, or montelukast may affect how other medicines work.

Tell your doctor if you are taking the following medicines before starting this medicine:

- 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)

Pregnancy and breast-feeding

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking montelukast. Your doctor will assess whether you can take this medicine during this time.

Use in breast-feeding

It is not known if montelukast appears in breast milk. You should consult your doctor before taking this medicine 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.

Montelukast contains the milk sugar lactose. If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Montelukast

- You should take only one tablet once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or an acute asthma attack.
- Always take this medicine 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. This medicine may be taken with food or without food.

If you are taking this medicine, be sure that you do not take any other products that contain the same active ingredient, montelukast.

If you take more Montelukast 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 Montelukast

Try to take this medicine 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 Montelukast

This medicine can treat your asthma only if you continue to take it.

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

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

4. Possible side effects

Like all medicines, this medicine 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 paediatric 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 montelukast 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, disturbance in attention, memory impairment (*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*); weakness/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.

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 the Yellow Card Scheme at: yellowcard.mhra.gov.uk

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

5. How to store Montelukast

Keep this medicine out of the sight and reach of children.

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

Store in the original package in order to protect from light and moisture.

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 protect the environment.

6. Contents of the pack and other information

What Montelukast film-coated tablets contain

The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 10 mg of montelukast.

The other ingredients are:

Tablet Core: lactose monohydrate, cellulose, microcrystalline (E460), croscarmellose sodium (E468), hydroxypropylcellulose (E463), magnesium stearate (E572).

Film-coating: hypromellose (E 464), titanium dioxide (E171), macrogol 400, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).

What Montelukast film-coated tablets look like and contents of the pack

Brown coloured rounded square shaped, film coated tablets debossed with 'MTS' on one side and '10' on the other side.

Blister in pack sizes of: 14, 20, 28, 49, 50, 100 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, HU17 0LD

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