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What is Montelukast and what it is used for

The full name of your medicine is Montelukast 10 mg Film-coated Tablets. Montelukast 10 mg Film-coated Tablets contains the active substance montelukast.

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. This medicine is indicated for patients 15 years of age and older.

- 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 are 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 in breathing because of narrowed airways. This narrowing of airways occurs 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 pollen pollens from trees, grasses, and weeds. The symptoms of seasonal allergies typically include:
- stuffy, runny nose; sneezing; watery, red, itchy eyes.

2. What you need to know before you take Montelukast

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, pharmacist or nurse before taking Montelukast.
- • If you are smaller or younger, tell your doctor immediately.
- • Montelukast is not meant to treat acute asthma attacks.
- • If an attack occurs, follow the instructions your doctor or pharmacist for advice before taking this medicine.

Children and adolescents

For children 2 to 5 years old, Montelukast 4 mg chewable tablets are available.

For children 6 to 14 years old, Montelukast 5 mg chewable tablets are available.

For children 6 months to 5 years old, Montelukast 4 mg granules are available.

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

Other medicines and Montelukast

Tell your doctor or pharmacist if you are taking the following medicines or Montelukast may affect how other medicines work. Some medicines may affect how Montelukast works or Montelukast may affect how other medicines work.

It is especially important to tell your doctor if you are taking the following medicines or Montelukast may affect how other medicines work.

- 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)

Montelukast with food, drink and alcohol

You may take Montelukast 10 mg tablets with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, consult your doctor before taking Montelukast. Montelukast may affect how other medicines work.

It is especially important to tell your doctor or pharmacist if you are taking the following medicines, Montelukast may affect how other medicines work.

- phenobarbital (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 Montelukast with other medicines

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

Pregnancy

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

Breast-feeding

It is not known if montelukast appears in breast milk. You should consult your doctor before taking Montelukast 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 your ability to drive or operate machinery.

Montelukast contains Lactose

• If you have had an allergic reaction to a medicine or drug that you have an intolerance to some sugar, contact your doctor before taking this medicine.

3. How to take Montelukast

Always take this medicine exactly as your doctor or pharmacist has told you.

How and when to take it

-• Montelukast is taken once a day. Please read section 4. How to handle the tablets.

-• Take Montelukast in the evening, about 30 minutes before going to bed. This helps control asthma attacks overnight.

-• Do not take Montelukast for a “run-down” or common cold. Montelukast is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor or pharmacist for advice before taking this medicine.

What is Montelukast?
Check with your doctor or pharmacist if you are not sure:
• You should take only one tablet of Montelukast 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. The tablet should be swallowed with a sufficient amount of fluid (for example with a glass of water).

The recommended dose
Use in adults and adolescents 15 years of age and older
The recommended dose is one 10 mg tablet to be taken daily in the evening. If you are taking Montelukast, be sure that you do not take any other products that contain the same active ingredient, montelukast.

Use in children and adolescents
For children 2 to 5 years old, Montelukast 4 mg chewable tablets are available. For children 6 to 14 years old, Montelukast 5 mg chewable tablets are available.

For children 6 months to 5 years old, Montelukast 4 mg granules are available.

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 hyperventilation.

If you forget to take Montelukast
Try to take Montelukast 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
Montelukast 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, pharmacist, or nurse.

6. 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 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).

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

Very rare (may affect up to 1 in 10,000 people)
• increased bleeding tendency
• palpitations
• tremor, disturbance in attention, memory impairment

Rare (may affect up to 1 in 1000 people)
• nausea
• diarrhea

Uncommon (may affect up to 1 in 100 people)
• increased appetite
• diarrhoea
• abdominal pain
• tiredness, feeling unwell
• joint or muscle pain, muscle cramps
• bruising, itching, hives
• dry mouth, indigestion
• nosebleed
• dizziness, drowsiness, 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 (See section 2). 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: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

7. Storage of 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 carton and blister (EXP). The expiry date refers to the last day of that month.
• This medicinal product does not require any special temperature storage conditions.

8. Contents of the pack and other information
What Montelukast contains
The active substance is montelukast. Each tablet contains 10.4 mg montelukast sodium which corresponds to 10 mg of montelukast.

The other ingredients are:
• Tablet core: lactose monohydrate (161.10 mg), microcrystalline cellulose (E460), croscarmellose sodium, magnesium stearate.
• Film coat: hypromellose 8c, hydroxypropyl cellulose (E467), Titanium dioxide (E171), iron oxide yellow (E172), isopropyl alcohol, iron oxide red (E172). What Montelukast look like and contents of the pack
Montelukast tablets are beige coloured, round, bi-convex, film-coated tablet, debossed SL 10 L. on one side and '10' on other side. Blister pack: Aluminium/Aluminium/Blister Pack size: 28, 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Bristol Laboratories Limited
Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom.
Telephone: 0044 (0)1442 200922
Fax: 0044 (0)1442 873717
Email: info@bl-labs.co.uk

Montelukast 10mg Film-Coated Tablets; PL 17907/0474

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