

Package Leaflet: Information for the user

Montelukast 10 mg

Film-coated Tablets

(Montelukast)

For adolescents and adults from 15 years of age

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Montelukast is 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 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

Do not take Montelukast

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

Talk to your doctor, pharmacist or nurse before taking Montelukast.

- If your asthma or breathing gets worse, tell your doctor immediately.
- 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 used instead of other asthma medications your doctor has prescribed.

- If you are on anti-asthma medicines, 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.

Various neuropsychiatric events (for example behaviour and mood-related changes, depression and suicidality) have been reported in patients of all ages treated with montelukast (see section 4). There have also been reports of these symptoms continuing after treatment is stopped. If you develop such symptoms while taking montelukast or if these symptoms do not resolve after montelukast is stopped, you should contact your prescriber.

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.

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

There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

Other medicines and Montelukast

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without a prescription. 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 before starting Montelukast:

- **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, think you may be pregnant or are planning to have a baby, ask 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 breastfeeding 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 patient's ability to drive or operate machinery.

Montelukast contains 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.

Information on sodium content:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Montelukast

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 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.

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 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 taking 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.

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 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).

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) (see Section 2)
- 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)

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

Very common (may affect more than 1 in 10 people)

- upper respiratory infection

Common (may affect up to 1 in 10 people)

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

Uncommon (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
- weakness/tiredness, feeling unwell, swelling bedwetting in children

Rare (may affect up to 1 in 1000 people)

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

Very rare (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

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 (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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 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. 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 to protect the environment.

6. 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 (116.10 mg), microcrystalline cellulose (E460), croscarmellose sodium, magnesium stearate.

Film coat: hypromellose 6cp, hydroxypropyl cellulose (E463), titanium dioxide (E171), iron oxide yellow (E172), carnauba wax, iron oxidered (E172).

What Montelukast look like and contents of the pack

Montelukast tablets are beige coloured, round, bi-convex, film-coated tablet, debossed with 'B 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
Email: info@bristol-labs.co.uk

Manufacturer

Bristol Laboratories Limited
Laporte Way Luton, Bedfordshire
LU4 8WL, United Kingdom

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