



Package leaflet: Information for the user

Montelukast 10mg film-coated tablets

montelukast sodium

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.

Pharmacode

What is in this leaflet

1. What Montelukast tablets is and what it is used for
2. What you need to know before you take Montelukast tablets
3. How to take Montelukast tablets
4. Possible side effects
5. How to store Montelukast tablets
6. Contents of the pack and other information

1. What Montelukast tablets are and what they are used for

What Montelukast tablets are

The name of your medicine is Montelukast 10mg film-coated tablets, and is referred to as Montelukast tablets throughout this leaflet. Montelukast tablets are a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Montelukast tablets works

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Montelukast tablets improve asthma symptoms, help control asthma and improve seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

When Montelukast tablets should be used

Your doctor has prescribed Montelukast tablets to treat asthma, preventing your asthma symptoms during the day and night.

- Montelukast tablets are used for the treatment of adults and adolescents 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
- Montelukast tablets also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast tablets are indicated in asthma, Montelukast tablets can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast tablets 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 tablets

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

Do not take Montelukast tablets

- 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 tablets.

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast tablets are 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 tablets 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.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood related changes) have been reported in adults, adolescents and children with Montelukast 10mg film-coated tablets (see section 4). If you develop(s) such symptoms while taking Montelukast 10mg film-coated tablets, you should consult your doctor.

Children and adolescents

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 tablets

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

Some medicines may affect how Montelukast tablets works, or Montelukast tablets may affect how other medicines work.

Tell your doctor if you are taking the following medicines before starting Montelukast tablets:

- 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 tablets with food and drink

Montelukast 10mg film-coated tablet may be taken with or without food.

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 Montelukast tablets.

Pregnancy

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

Breast-feeding

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

Driving and using machines

Montelukast tablets 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 with montelukast may affect some patients' ability to drive or operate machinery.

This medicine contains 1.5 mg aspartame in each film-coated tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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

3. How to take Montelukast tablets

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 tablets once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.

For adults and adolescents 15 years of age and older

The recommended dose is one 10mg tablet to be taken daily in the evening.

If you are taking Montelukast tablets, be sure that you do not take any other products that contain the same active ingredient, montelukast. This medicine is for oral use.

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

If you take more Montelukast tablets 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 tablets

Try to take Montelukast tablets 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 tablets

Montelukast tablets can treat your asthma only if you continue to take it.

It is important to continue taking Montelukast tablets 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 10mg 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 side effects (may affect more than 1 in 10 people):

- Upper respiratory infection.

Common side effects (may affect up to 1 in 10 people):

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

Uncommon side effects (may affect up to 1 in 100 people):

- nose bleed
- dry mouth
- indigestion
- bruising
- itching
- hives
- joint and / or muscle pain, muscle cramps
- bedwetting in children
- pins and needles/ numbness
- weakness/ tiredness
- feeling unwell
- swelling
- feeling dizzy
- feeling drowsy

Behaviour and mood related changes, such as:

- dream abnormalities
- nightmares
- trouble sleeping
- sleep walking
- irritability
- feeling anxious
- restlessness

Rare side effects (may affect up to than 1 in 1,000 people):

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

Very rare side effects (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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 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 tablets

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 the carton. 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 packaging to protect from light.

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 tablets contains**

- The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 10mg of montelukast.
- The other ingredients are:
 - Tablet core
mannitol spray dried, cellulose microcrystalline, low-substituted hydroxypropyl cellulose, croscarmellose sodium, banana flavour, aspartame, magnesium stearate.
 - Coating
Hypromellose 3cP, hydroxypropyl cellulose, talc, titanium dioxide, iron oxide yellow (E 172), iron oxide red (E 172).

What Montelukast tablets looks like and contents of the pack

Beige, round, biconvex, film-coated tablets.
Blisters in packages of 7, 10, 14, 20, 28, 30, 50, 56, 90 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Medley Pharma Ltd
Unit 2A, Olympic Way,
Sefton Business Park,
Bootle, Merseyside,
L30 1RD, United Kingdom

Manufacturer

Genepharma S.A.
18th km Marathonos Ave,
Pallini Attiki, 15351
Greece

This leaflet was last revised in 07/2024

XX-XXXXXX-XX

567/01