

PACKAGE LEAFLET: INFORMATION FOR THE USER

Montelukast 10 mg tablets

For adolescents and adults from 15 years

montelukast

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.

What is in this leaflet:

1. What Montelukast tablets are and what they are 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

Montelukast tablets are a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Montelukast tablets work

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 help 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, or 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 acetylsalicylic 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). If you develop such symptoms while taking montelukast, you should contact 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, 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

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

Montelukast tablets contains aspartame

Montelukast tablets contain aspartame, a source of phenylalanine. If you have phenylketonuria (a rare, hereditary disorder of the metabolism), you should take into account that each 10-mg tablet contains aspartame (equivalent to 0.421 mg phenylalanine per 10-mg tablet).

Montelukast tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per chewing 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 10 mg 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 with or without food. The tablet should be swallowed with a sufficient amount of fluid (e.g. with a glass of water).

The tablet can be divided into equal doses.

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. They 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 medicines can cause side effects, although not everybody gets them.

In clinical studies with montelukast 10 mg, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast 10 mg were::

- abdominal pain
- headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast 10 mg s 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: 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: may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: 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)

Other side effects while the medicine has been on the market

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
- rash
- fever
- elevated liver enzymes

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

Rare: may affect up to 1 in 1,000 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

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: 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 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 carton and blister after 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 tablets contain

- The active substance is montelukast. Each tablet contains 10.4 mg montelukast sodium which corresponds to 10 mg of montelukast.

- The other ingredients are: mannitol (E421), cellulose microcrystalline, croscarmellose sodium, magnesium stearate, aspartame (E951), cherry flavour (Firmenich CHERRY 501027 AP0551), iron oxide yellow (E172), iron oxide red (E172).

What Montelukast tablets look like and contents of the pack

Montelukast 10 mg tablets are light brown coloured, round biconvex shaped, uncoated tablet, with breakline on both sides.

Tablets are packed into Alu/Alu blisters. The blisters are packed into cartons.

Pack sizes: 28 tablets.

Marketing Authorisation Holder and Manufacturer

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Colour Black

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SIZE : 180 x 300 mm_Front/Back Side	CODE : 8095253-7803	DATE : 05-01-2024		
REMARK : Folding Length 35 mm				
SUBSTRATE :				
Activities	Department	Name	Signature	Date
Prepared By	Pkg.Dev			
Reviewed By	Pkg.Dev			
Approved By	Quality			



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