

PACKAGE LEAFLET: INFORMATION FOR THE USER

Montelukast 10 mg Film-coated Tablets

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 10 mg Film-coated Tablets is and what it is used for
2. What you need to know before you take Montelukast 10 mg Film-coated Tablets
3. How to take Montelukast 10 mg Film-coated Tablets
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1. What Montelukast 10 mg Film-coated Tablets is and what it is used for

Montelukast 10 mg Film-coated Tablets is a leukotriene receptor antagonist that blocks the substance called leukotrienes. Leukotrienes can cause the narrowing and swelling of airways in your lungs and also cause allergy symptoms. By blocking leukotrienes, this medicine 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 10 mg Film-coated Tablets to treat asthma, preventing your asthma symptoms during the day and night.

- This medicine is 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.
- This medicine also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom this medicine 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 in breathing because of the 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 pollen from trees, grass and weeds. The symptoms of seasonal allergies typically may include stuffy, runny, itchy nose; sneezing; watery, swollen, red and itchy eyes.

2. What you need to know before you take Montelukast 10 mg Film-coated Tablets

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

Do not take Montelukast 10 mg Film-coated 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 this medicine.

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast 10 mg Film-coated Tablets is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have with you, your inhaled rescue medicine for asthma attack.
- 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.
- It is important that you or your child takes all asthma medicines as prescribed by your doctor.

Montelukast should not be used in place of other asthma medications your doctor has prescribed for you.

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.

For children from the age of 2 to 5 years old, Montelukast 4 mg Chewable Tablets are available.

For children from the age of 6 to 14 years old, Montelukast 5 mg Chewable Tablets are available.

For children 6 months to 5 years 4mg granules are also available.

Other medicines and Montelukast 10 mg Film-coated Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those medicines obtained without a prescription. This includes medicines, herbal remedies, health products or supplements that you have obtained without a prescription.

Treatment with Montelukast 10 mg Film-coated Tablets can be affected by other medicines. Some medicines may affect how montelukast works, or montelukast may affect how other medicines work. Tell your doctor if you are taking any of the following medicines before starting Montelukast 10 mg Film-coated 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).

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

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

Breast-feeding

It is not known if this medicine 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

This medicine 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 this medicine may affect some patients ability to drive or operate machinery, therefore caution is advised.

Montelukast 10 mg Film-coated Tablets contains lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (rare hereditary problems, galactose intolerance, the lapp lactose deficiency of glucose-galactose malabsorption), you should contact your doctor before taking this medicine.

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

3. How to take Montelukast 10 mg Film-coated 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 this medicine 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.

For adults and adolescents aged 15 years and older

The recommended dose is one 10 mg tablet to be taken daily in the evening. This medicine may be taken with 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 10 mg Film-coated Tablets than you should

If you take more 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 adolescents included abdominal pain, sleepiness, thirst, headache, vomiting and hyperactivity (unusually active).

If you forget to take Montelukast 10 mg Film-coated Tablets

Try to take this medicine as recommended to you by your doctor. However, if you miss a dose, just take your tablet as soon as you remember. Take your next dose of one tablet once daily at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Montelukast 10 mg Film-coated Tablets

This medicine can treat your asthma only if you continue to take it. It is important to continue taking this medicine as prescribed to you by your doctor. 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 (may affect up to 1 in 10 people) thought to be related to this medicine 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 at:

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 10 mg film-coated 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 after EXP. The expiry date refers to the last day of that month.

HDPE container:

Use within 30 days of opening. Once the pack has been opened write the date of opening on the space provided on the package label and also write the date by when the product should be used.

Store the medicine in the original package to protect from moisture. This medicinal product does not require any special temperature storage conditions.

Aluminium/aluminium blisters:

Store in the original package to protect from moisture. Do not store above 30°C.

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 10 mg Film-coated Tablets contains

- The active substance is montelukast sodium. Each tablet contains montelukast sodium which corresponds to 10 mg of montelukast.
- The other ingredients are:

Core:

Cellulose microcrystalline
Lactose monohydrate
Croscarmellose sodium
Hydroxypropylcellulose (E463)
Magnesium stearate

Film-coating:

Hypromellose (E464)
Hydroxypropylcellulose (E463)
Titanium dioxide (E171)
Iron Oxide yellow (E172)
Carnauba wax (E903)
Iron Oxide red (E172)

What Montelukast 10 mg Film-coated Tablets looks like and contents of the pack

10 mg tablets are beige, round, 8 mm biconvex, film-coated tablets, engraved with 'G' on one side and '392' on the other side.

Montelukast 10 mg Film-coated Tablets are available in Aluminium/Aluminium blister pack or HDPE containers in cardboard carton with polypropylene child resistant closure and silica gel desiccant canister.

Pack sizes: 20, 28, 30, 50 and 100.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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