Package leaflet: Information for the patient
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

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1. What Montelukast 10 mg film-coated tablets are and what they are used for

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, 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 this medicine to treat asthma, preventing your asthma symptoms during the day and night.

- This medicine is used for the treatment of 15 years of age and older patients 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 15 years of age and older asthmatic patients in whom this medicine is indicated in asthma, this can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how these tablets should be used depending on the symptoms and severity of your asthma.

What is asthma?
Asthma is a long-term disease.

Asthma includes:

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• 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 10 mg film-coated tablets**

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

- If your asthma or breathing gets worse, tell your doctor immediately.
- This oral medicine 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.
- This medicine 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 aspirin (acetylsalicylic acid) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

**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.
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.

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

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 and drink
These 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 this 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 tablet during this time.

Breast-feeding
It is not known if this medicine appears in breast milk. You should consult your doctor before taking this tablet 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 Montelukast may affect some patients' ability to drive or operate machinery.

Montelukast 10 mg film-coated tablets contain 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.

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 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
For adults 15 years of age and older:
One 10 mg tablet to be taken daily in the evening. This tablet 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 than you should
Contact your doctor immediately for advice. There were no side effects reported in the majority of over dose 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 this medicine 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
This medicine can treat your asthma only if you continue to take it. It is important to continue taking this medicine 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.

Serious side effects
If you experience any of the following, stop taking the medicine and tell your doctor immediately or go to the casualty department of your nearest hospital.

- **Allergic reactions:** If you have allergic reactions, **stop having this medicine and see a doctor straight away.** You may need urgent medical treatment. The signs may include rashes, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing.
- **Behaviour and mood related changes:** Suicidal thoughts and actions.
- **Churg-Strauss syndrome:** Symptoms include flu like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash.

Other side effects
In clinical studies with Montelukast 10 mg film-coated tablets, the 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 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).

**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
- changes in liver function test
- rash
- fever

**Uncommon: may affect up to 1 in 100 people**
- dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression
- dizziness, drowsiness, pins and needles/numbness, seizure
- nose bleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- tiredness, feeling unwell, swelling

**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**
- hallucinations, disorientation
- hepatitis (inflammation of the liver)
- tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reaction (erythema multiforme) that may occur without warning

**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](http://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 and blister after EXP. The expiry date refers to the last day of that month.
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 protect the environment.

6. Contents of the pack and other information

What Montelukast 10-mg film-coated tablets contain
• The active substance is: montelukast. Each tablet contains montelukast sodium which corresponds to 10 mg of montelukast.
• The other ingredients are: Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate. Film coating: Opadry Yellow 03B 52874 (hypromellose, titanium dioxide, macrogol, iron oxide yellow, iron oxide red)

What Montelukast 10-mg film-coated tablets look like and contents of the pack
Montelukast 10 mg film-coated tablets are beige to light yellow coloured, rounded square, film-coated tablets, engraved with “M10” on one side and plain on the other side.
Blisters in packages of: 14, 28, 30, 50, 56, 98 tablets.
Not all pack sizes may be marketed

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