

Package leaflet: Information for the patient

Montelukast 10 mg film-coated tablets For adolescents and adults from 15 years of age

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, 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:

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

1. What Montelukast is and what it is 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, 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.

- Montelukast is used for the treatment of patients 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
- Montelukast also helps prevent the narrowing of airways triggered by exercise for patients 15 years of age and older.
- In those asthmatic patients 15 years of age and older in whom Montelukast is 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.

2. What you need to know before you take Montelukast

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

Do not take Montelukast

- 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, pharmacist or nurse before taking Montelukast.
- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral 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 take all asthma medications prescribed by your doctor.
- Montelukast should not be used instead of 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 other non-steroidal anti-inflammatory drugs (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 (see section 4). If you or your child develop(s) such symptoms while taking Montelukast you should consult your or your child's doctor.

Children

For children aged 6 months to 14 years, other strengths and pharmaceutical forms of montelukast may be available.

Other medicines and Montelukast

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Montelukast may be taken with or without food.

Pregnancy and breast-feeding

Use in pregnancy

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.

Use in breast-feeding

It is not known if Montelukast appears in breast milk. You should consult your doctor before taking Montelukast if you are breast-feeding or intend to breast-feed. Your doctor will assess whether you can take Montelukast during this time.

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 patients' 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.

3. How to take Montelukast

- 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.
- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- To be taken by mouth.

The recommended dose for patients 15 years of age and older is one 10 mg tablet to be taken daily in the evening. Montelukast 10 mg may be taken with or without food.

If you are taking Montelukast, 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 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 take 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.

If you notice any of the following serious side effects that have been reported with montelukast, stop taking Montelukast and contact a doctor immediately:

- sudden wheezing, swelling of lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction). This side effect is uncommon (may affect up to 1 in 100 people).
- flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome). This side effect is very rare (may affect up to 1 in 10,000 people).
- suicidal thoughts and actions. This side effect is very rare (may affect up to 1 in 10,000 people).
- severe skin reactions (erythema multiforme) that may occur without warning. This side effect is very rare (may affect up to 1 in 10,000 people).

The following side effects have also been reported with montelukast:

Very common: may affect more than 1 in 10 people

- colds (upper respiratory infection)

Common: may affect up to 1 in 10 people

- headache
- abdominal pain
- thirst
- diarrhoea, nausea, vomiting
- rash
- fever
- asthma
- hyperactivity
- red, itchy skin (eczema)
- increased amounts of certain substances in the blood (transaminases)

Uncommon: may affect up to 1 in 100 people

- behaviour and mood related changes (dream abnormalities, including nightmares, irritability, sleepwalking, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression, trouble sleeping)
- dizziness, drowsiness, pins and needles/numbness, seizures (fits)

- nosebleed
- 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

- tremor, disturbance in attention, memory impairment
- increased bleeding tendency
- shaking
- feeling your heartbeat (palpitations)
- swelling of the skin

Very rare: may affect up to 1 in 10,000 people

- hallucinations, confusion, stuttering
- hepatitis (inflammation of the liver), liver problems (hepatic eosinophilic infiltration)
- tender red lumps under the skin most commonly on your shins (erythema nodosum)

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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Montelukast

Keep 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 store above 30°C.

Do not throw away 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 contains

- The active substance is montelukast. Each film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast
- The other ingredients are *tablet core*: microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate; *film-coat*: lactose monohydrate, hypromellose 15cP, titanium dioxide (E171), macrogol 4000, iron oxide yellow (E172), iron oxide red (E172)

What Montelukast looks like and contents of the pack

Film-coated tablet

Beige, square, biconvex size 7.9 mm x 7.9 mm film-coated tablets with M engraved on one side

Blister (OPA-Al-PVC/Al):

10, 14, 20, 28, 30, 50, 56, 98, 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Actavis Limited
BLB016 Bulebel Industrial Estate
Zejtun ZTN 3000
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Montelukast 10 mg Film-coated tablets
United Kingdom	Montelukast 10 mg Film-coated tablets

This leaflet was last revised in July 2019