

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 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

What MONTELUKAST is

MONTELUKAST is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How MONTELUKAST works

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).

When MONTELUKAST should be used

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

- MONTELUKAST 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.
- MONTELUKAST also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients 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.

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 lining of 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

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 or pharmacist 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 or your child take all asthma medications prescribed by your doctor. MONTELUKAST 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 NSAID's) 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 child's 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

Tell your doctor or pharmacist if you are taking or 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

MONTELUKAST 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

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

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.

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 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

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.

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, 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 10 mg with or without food.

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 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 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)

Other side effects while the medicine has been on the market

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: the following may affect up to 1 in 10 people

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

Uncommon: the following 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: the following may affect up to 1 in 1,000 people

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

Very rare: the following 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

HPRA 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 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/label/bottle after EXP. The expiry date refers to the last date of that month.

Store below 25°C.

Store in the original package in order to protect from light and moisture.

Use within 30 days after first opening the HDPE bottle.

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 contains

- The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 10 mg of montelukast.
- The other ingredients are:
Tablet Core: Cellulose, microcrystalline (E460), lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose (E463), magnesium stearate (E572).

Film coating: Hydroxypropyl cellulose (E463), hypremellose 6cP (E464), titanium dioxide (E171), iron oxide yellow (E172), carnuba wax (E903), iron oxide red (E172).

What MONTELUKAST looks like and contents of the pack

Film-coated tablets

Beige coloured, rounded square shaped, film-coated tablets debossed with 'X' on one side and '54' on other side.

Polyamide / Aluminium foil / PVC – Aluminium foil blisters

Pack sizes: 7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98, 100, 140 and 200 tablets

HDPE bottle with polypropylene cap containing silica gel desiccant:
Pack sizes: 30 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

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

France	MONTELUKAST ARROW Lab 10 mg, comprimé pelliculé
Germany	Montelukast Aurobindo 10 mg Filmtabletten
Ireland	MONTELUKAST 10 mg Film-Coated Tablets
Italy	Montelukast Aurobindo 10mg compresse rivestite con film
Malta	Montelukast Aurobindo 10mg film-coated tablets
Netherlands	Montelukast Aurobindo 10 mg, filmomhulde tabletten
Poland	Montelukast Aurovitass
Portugal	Montelucaste Aurobindo
Romania	Montelukast Aurobindo 10 mg comprimate filmate
Spain	Montelukast Aurovitass 10 mg comprimidos recubiertos con película EFG
United Kingdom	Montelukast 10mg film-coated tablets

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