

## **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 are and what they are 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
4. Possible side effects
5. How to store Montelukast 10 mg film-coated tablets
6. Contents of the pack and other information

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

##### **What Montelukast 10 mg film-coated tablets is**

Montelukast 10 mg film-coated tablets are leukotriene receptor antagonist that blocks substances called leukotrienes.

##### **How Montelukast 10 mg film-coated tablets works**

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Montelukast 10 mg film-coated tablets improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

##### **When Montelukast 10 mg film-coated tablets should be used**

Your doctor has prescribed Montelukast 10 mg film-coated tablets to treat asthma, preventing your asthma symptoms during the day and night.

- Montelukast 10 mg film-coated 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 10 mg film-coated tablets also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast 10 mg film-coated tablets are indicated in asthma, Montelukast 10 mg film-coated tablets can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast 10 mg film-coated 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, cold air, or exercise.
- swelling (inflammation) in the 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 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 10 mg film-coated tablets

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast 10 mg film-coated 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 10 mg film-coated 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 acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or 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 10 mg film-coated tablets (see section 4). If you develop such symptoms while taking Montelukast 10 mg film-coated tablets, you should consult 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 10 mg film-coated tablets**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Some medicines may affect how Montelukast 10 mg film-coated tablets works, or Montelukast 10 mg film-coated tablets may affect how other medicines work.

Tell your doctor if you are taking 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)

**Montelukast 10 mg film-coated tablets with food and drink**

Montelukast 10 mg film-coated 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 10 mg film-coated tablets.

**Pregnancy**

Your doctor will assess whether you can take Montelukast 10 mg film-coated tablets during this time.

**Breast-feeding**

It is not known if montelukast appears in human milk. You should consult your doctor before taking Montelukast 10 mg film-coated tablets if you are breast-feeding or intend to breast-feed.

**Driving and using machines**

Montelukast 10 mg film-coated 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 10 mg film-coated tablets may affect some patients' ability to drive or operate machinery.

**Montelukast 10 mg film-coated tablets contains lactose**

Montelukast 10 mg film-coated tablets 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 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 10 mg film-coated 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 10 mg film-coated tablets, be sure that you do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.  
Montelukast 10 mg film-coated tablets may be taken with or without food.

#### **If you take more Montelukast 10 mg film-coated 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 10 mg film-coated tablets**

Try to take Montelukast 10 mg film-coated 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 10 mg film-coated tablets**

Montelukast 10 mg film-coated tablets can treat your asthma only if you continue to take it.

It is important to continue taking Montelukast 10 mg film-coated tablets 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). 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 Montelukast 10 mg film-coated tablets after the expiry date which is stated on the label or carton 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.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Montelukast 10 mg film-coated tablets contains**

The active substance is Montelukast. Each film-coated tablet contains 10 mg of montelukast.

The other ingredients are:

Tablet core: Lactose monohydrate, cellulose microcrystalline, low substituted hydroxypropylcellulose (LH-11) (E 463), croscarmellose sodium, magnesium stearate.

Film coat: Hydroxypropylcellulose (LF) (E 463), hypromellose 6CPS (A), titanium dioxide (E 171), macrogol 6000, iron oxide yellow and iron oxide red (E172) (*see section 2 for Important information about some of the ingredients of <Montelukast 10 mg film-coated tablets>*).

### **What Montelukast 10 mg film-coated tablets looks like and contents of the pack**

Montelukast 10 mg film-coated tablets are 7.9 x 7.9 mm beige coloured, rounded square, biconvex, film coated tablet debossed "M10" on one side and plain on other side.

Montelukast 10 mg film-coated tablets are available in OPA-Al-PVC/Al blister pack of 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140 and 200 tablets.

(Not all pack sizes may be marketed).

**Marketing Authorisation Holder**

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

**Manufacturer**

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North Harrow, Middlesex HA1 4HF,  
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Accord Healthcare Polska Sp.z o.o.,  
ul. Lutomierska 50,95-200 Pabianice, Poland

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

<b>Name of the Member State</b>	<b>Name of the medicinal product</b>
Austria	Montelukast Accord 10 mg Filmtabletten
Bulgaria	Montelukast Accord 10 mg филмирани таблетки
Denmark	Montelukast Accord Healthcare
Estonia	Montelukast Accord
Finland	Montelukast Accord 10 mg Kalvopäävysteininen Tabletti/ filmdragerade tabletter
France	MONTELUKAST ACCORD HEALTHCARE 10 mg comprimés pelliculés
Ireland	Montelukast 10 mg Film-coated Tablets
Italy	Montelukast Accord 10 mg compresse rivestite con film
Latvia	Montelukast Accord 10 mg apvalkotās tableti
Malta	Montelukast 10 mg Film-coated Tablets
Norway	Montelukast Accord 10 mg Filmdrasjerte tabletter
Portugal	Montelucaste Accord
Spain	Montelukast Accord 10 mg comprimidos recubiertos con película EFG
Sweden	Montelukast Accord 10 mg filmdragerade tabletter
The Netherlands	Montelukast 10 mg Filmomhulde tabletten
United Kingdom	Montelukast 10 mg Film-coated Tablets

**This leaflet was last revised in 09/2020.**