

## Montelukast 10 mg Film-coated Tablets

For adolescents and adults from 15 years  
montelukast

### Package leaflet: Information for the user

**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
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 is and what it is used for

Montelukast 10 mg Film-coated Tablets are 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 10 mg Film-coated Tablets improves asthma symptoms, helps control asthma and improve seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

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

Montelukast 10mg Film-coated Tablets are used for the treatment of patients 15 years of age and older who are not adequately controlled on their asthma medications and need additional therapy. For patients with asthma and seasonal allergies, Montelukast 10mg Film-coated Tablets also treat your seasonal allergy symptoms.

Montelukast 10mg Film-coated Tablets, in patients 15 years of age and older, help prevent asthma symptoms which are triggered by exercise.

### What is asthma?

Asthma is 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, or 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

### Do not use Montelukast 10 mg Film-coated Tablets

- if you are allergic to montelukast sodium 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

- It is important that Montelukast 10mg Film-coated Tablets are taken daily in the evening as prescribed by your doctor even when you have no symptoms, or if you experience an asthma attack.
- Oral Montelukast 10mg Film-coated Tablets are NOT intended for the treatment of a sudden attack of breathlessness. They will not help you in this situation and should never be used for this purpose. If an attack occurs, the instructions that the doctor has given should be followed exactly. It is very important to have the

medication needed for such an attack readily accessible at all times. Always have your inhaled rescue medicine for asthma attacks with you.

- If you need to use your beta-agonist inhaler more often than usual, you should consult your doctor as soon as possible.
- It is important that you use all the asthma medication prescribed by the doctor as intended. Montelukast 10mg Film-coated Tablets should not replace steroid medications (whether inhaled or taken by mouth) that you may be already using.
- Patients with aspirin-sensitive asthma taking Montelukast 10mg Film-coated Tablets must continue to avoid taking aspirin or other non-steroidal anti-inflammatory drugs.
- If you are taking anti-asthma medicines, including montelukast, you may experience a combination of symptoms: flu-like illness, increasing breathlessness, pins and needles or numbness of limbs, and/or rash, you should consult your doctor.

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 or your child develop(s) such symptoms while taking Montelukast 10 mg Film-coated Tablets, you should consult your or your child's doctor.

Montelukast 10mg Film-coated Tablets are not recommended for use in children under the age of 15.

### Other medicines and Montelukast 10 mg Film-coated Tablets

Montelukast 10 mg Film-coated Tablets may be used together with other medicines you may be taking for asthma. However, some medicines can interfere with Montelukast 10 mg Film-coated Tablets, or Montelukast 10 mg Film-coated Tablets may affect how other medicines work.

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 is particularly important if the other medicine is:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections).

### Montelukast 10 mg Film-coated Tablets with food and drink

Montelukast 10 mg Film-coated Tablets may be taken in the evening with or without food.

### Pregnancy, breast-feeding and fertility

Pregnancy:

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

Breast feeding:

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

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

### Driving and using machines

Montelukast 10mg 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 may affect some patients' ability to drive or operate machinery have been reported very rarely for montelukast

### 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.

### Montelukast 10 mg Film-coated Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated 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, even when you have no symptoms, or if you experience an asthma attack. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and adolescents aged 15 years upwards is one 10 mg tablet daily in the evening.  
This medicine is for oral use.

Montelukast 10mg Film-coated Tablets should not be used together with other products that contain the same active ingredient, montelukast.

**If you take more Montelukast 10mg Film-coated Tablets than you should**

It is important not to take too many tablets. Contact your nearest hospital Accident and Emergency department or a doctor for advice if you have swallowed too many tablets or if you think a child has swallowed any. Symptoms of overdose include abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity (involuntary movement). Take this leaflet and any of the remaining tablets with you to show the doctor.

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

If you forget to take a tablet, just carry on with the next one as usual. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Montelukast 10mg Film-coated Tablets**

It is important to continue taking Montelukast 10mg Film-coated Tablets in the presence or absence of symptoms, for as long as your doctor prescribes them, in order to help control of your asthma. Montelukast 10mg Film-coated Tablets can treat asthma only with continued use.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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

For children 2 to 5 years old who have problems taking a chewable tablet, a 4 mg granule formulation is available

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

**4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies with montelukast, 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 10 mg Film-coated Tablets 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: may affect up to 1 in 100 people
- allergic reactions including rash, 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: 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

- 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)
- 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: may affect more than 1 in 10 people

- upper respiratory infection

Common: may affect up to 1 in 10 people

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

Uncommon: may affect up to 1 in 100 people

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleep walking, 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: may affect up to 1 in 1,000 people

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

Very rare: 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](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 blister and carton after EXP. The expiry date refers to the last day of that month.

No special storage conditions. Keep the blister in outer carton in order to protect from light.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. 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 10.40mg montelukast sodium, which is equivalent to 10 mg of montelukast.

- The other ingredients are:

tablet core: sodium laurilsulfate, lactose monohydrate, hydroxypropyl cellulose, pregelatinized starch (maize), sodium starch glycolate (maize) Type A, magnesium stearate, tablet coating: Opadry 20A23676 Yellow containing hydroxypropyl cellulose, hypromellose, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172).

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

Montelukast 10 mg Film-coated Tablets are beige, round, film-coated tablets, debossed with "93" on one side and "7426" on the other side of the tablet

Montelukast 10 mg Film-coated Tablets are available in packs of 7, 14, 15, 20, 28, 30, 50, 56, 60, 90, 98 and 100 tablets and calendar packs of 7, 14, 28, 56 and 98 tablets.

Aluminium – Aluminium blister packs

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

**Manufacturer:** Teva Operations Poland Sp. z o.o. Ul. Mogilska 80, 31-546 Kraków

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