Package leaflet: Information for the user

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

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 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

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 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 NSAIDs) if they make your asthma worse.

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 develop such symptoms while taking montelukast, you should contact your doctor.

Children
Do not give this medicine to children less than 15 years of age.
There are different forms 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 including those obtained without a prescription.

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).

Taking Montelukast with food
Montelukast 10 mg 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 contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
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

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 to 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: 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) (see section 2),
- low blood platelet count,
- behavioural 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 reported 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,
- rash,
- fever,
- elevated liver enzymes.

Uncommon: the following may affect up to 1 in 100 people

- behavioural 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: may affect up to 1 in 1,000 people
- behavioural 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),
- behavioural 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, Website: www.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 blister and carton after EXP. The expiry date refers to the last day of that month.

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

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 film-coated tablet contains 10 mg montelukast (as montelukast sodium).
- The other ingredients are lactose monohydrate, powdered cellulose, microcrystalline cellulose, croscarmellose sodium and magnesium stearate in the tablet core, and hypromellose, titanium dioxide (E171), talc, propylene glycol, red iron oxide (E172) and yellow iron oxide (E172) in the film coating. See section 2 "Montelukast contains lactose and sodium".

What Montelukast looks like and contents of the pack
The film-coated tablets are apricot-coloured, round, slightly biconvex, with bevelled edges.

Boxes of 7, 10, 14, 20, 28, 30, 49, 50, 56, 84, 90, 98, 100, 140 or 200 film-coated tablets in blisters are available.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
KRKA Polska Sp. z o.o., ul. Równoległa 5, 02-235 Warsaw, Poland
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Bulgaria, Estonia, Lihtuania, Poland, Czech Republic, Germany, Spain, Italy, Latvia, Romania, Slovakia; Malta	Monkasta
Denmark, Finland, Norway, Austria, Belgium, Cyprus, France, Netherlands, Sweden	Montelukast Krka
Ireland, United Kingdom (Northern Ireland)	Montelukast
Hungary	Monalux
Portugal	Montelucaste Krka

This leaflet was last revised in

Detailed information on this medicine is available on the website of HPRA (www.hpra.ie|)