

Package leaflet: Information for the user

## Montelukast 4 mg chewable tablets

### For children from 2 to 5 years

Montelukast

**Read all of this leaflet carefully before you start giving this medicine to your child 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets 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 your child takes 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. By blocking leukotrienes, Montelukast improves asthma symptoms and helps control asthma.

#### When Montelukast should be used

- Your doctor has prescribed Montelukast to treat your child's asthma, preventing asthma symptoms during the day and night.
- Montelukast is used for the treatment of 2 to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
  - Montelukast may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
  - Montelukast also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Montelukast should be used depending on the symptoms and severity of your child's 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.

## 2. What you need to know before your child takes Montelukast

Tell your doctor about any medical problems or allergies your child has now or has had.

#### Do not give Montelukast to your child:

- if your child is 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 you give Montelukast to your child.

- If your child's 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 for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- It is important that your child take all asthma medications prescribed by your doctor. Montelukast should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- Your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/her 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 treated with

Montelukast (see section 4). If your child develops such symptoms while taking Montelukast, you should consult your child's doctor.

#### Children and adolescents

Do not give this medicine to children less than 2 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 your child is taking or has recently been given or might be given 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 your child is 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).

#### Montelukast with food and drink

Montelukast 4 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

#### Pregnancy and breast-feeding

This subsection is not applicable for Montelukast 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age.

#### Driving and using machines

This subsection is not applicable for the Montelukast 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

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 aspartame and sodium

This medicine contains 1.2 mg aspartame in each chewable tablet. Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially "sodium-free".

## 3. How to take Montelukast

Always have your child take this medicine exactly as your doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.

- This medicine is to be given to a child under adult supervision. For children who have problems consuming a chewable tablet, an oral granule formulation is available.
- Your child should take only one chewable tablet of Montelukast once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

#### Use in children 2 to 5 years of age:

The recommended dose is one 4 mg chewable tablet daily to be taken in the evening.

If your child is taking Montelukast, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

This medicine is for oral use.

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The tablets are to be chewed before swallowing.

Montelukast 4 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

**If your child takes more Montelukast than he/she should**  
Contact your child's 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 give Montelukast to your child**

Try to give Montelukast as prescribed. However, if your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

Do not give a double dose to make up for a forgotten dose.

**If your child stops taking Montelukast**

Montelukast can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking Montelukast for as long as your doctor prescribes. It will help control your child's asthma.

If you have any further questions on the use of this medicine, ask your child's 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 4 mg chewable tablets, the most commonly reported side effect (may affect up to 1 in 10 people) thought to be related to treatment with montelukast were:

- abdominal pain,
- thirst.

Additionally, the following side effect was reported in clinical studies with montelukast 10 mg film-coated tablets and 5 mg chewable tablets:

- headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill containing no active substance).

#### Serious side effects

**Talk to your child's doctor immediately** if you notice any of the following side effects, which may be serious, and for which your child 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

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 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 chewable tablets contain

- The active substance is montelukast.  
Each chewable tablet contains 4 mg montelukast (as montelukast sodium).
- The other ingredients are mannitol (E421), microcrystalline cellulose, croscarmellose sodium, hydroxypropylcellulose, aspartame (E951), red iron oxide (E172), flavour cherry black (also contains glyceryl triacetate (E1518)) and magnesium stearate.  
See section 2 "Montelukast contains aspartame and sodium".

##### What Montelukast chewable tablets looks like and contents of the pack

Pink, marbled, round, slightly biconvex tablets with bevelled edges and inscription 4 on one side.

Boxes of 7, 10, 14, 20, 28, 30, 49, 50, 56, 84, 90, 98, 100, 140 or 200 chewable tablets in blisters are available.

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

Bulgaria, Estonia, Lithuania, Poland, Czech Republic, Germany, Spain, Italy, Latvia, Romania, Slovakia	Monkasta
Denmark, Finland, Norway, Austria, Belgium, Cyprus, Greece, France, Netherlands, Sweden	Montelukast Krka
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Hungary	Monalux
Portugal	Montelucaste Krka

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