

## Package leaflet: Information for the user

### Montelukast 4 mg granules For children from 6 months to 5 years of age

**Read all of this leaflet carefully before you give this medicine to your child because it contains important information.**

- 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 of the 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 granules is and what it is used for
2. What you need to know before your child takes Montelukast granules
3. How to take Montelukast granules
4. Possible side effects
5. How to store Montelukast granules
6. Contents of the pack and other information

#### 1. What Montelukast granules is and what it is used for

##### What Montelukast granules is

Montelukast granules is a leukotriene receptor antagonist that blocks substances called leukotrienes.

##### How Montelukast granules works

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast granules improves asthma symptoms and help control asthma.

##### When Montelukast granules should be used

Your doctor has prescribed Montelukast granules to treat your child's asthma, preventing asthma symptoms during the day and night.

- Montelukast granules is used for the treatment of 6 months to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast granules 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 granules also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Montelukast granules 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 the airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

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

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

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

- if he/she is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

Talk to your child's doctor or pharmacist before you give Montelukast granules to your child

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast granules 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 granules 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.

**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 your child develops such symptoms while taking Montelukast granules, you should consult your child's doctor.**

##### Children and adolescents

Do not give this medicine to children less than 6 months 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 granules

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 granules works, or Montelukast granules may affect how your child's other medicines work.

Tell your doctor if your child is taking the following medicines before starting Montelukast granules:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used to treat is hypertriglyceridaemia, mixed hyperlipidaemia and primary hypercholesterolaemia).

##### Montelukast granules with food and drink

Montelukast granules can be taken without regard to the timing of food intake.

##### Pregnancy and breast-feeding

This subsection is not applicable for Montelukast 4 mg granules since it is intended for use in children 6 months to 5 years of age.

##### Driving and using machines

This subsection is not applicable for Montelukast 4 mg granules since it is intended for use in children 6 months 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 and use machines. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with montelukast may affect some patients' ability to drive or operate machinery.

##### Montelukast granules contains sodium

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

#### 3. How to take Montelukast granules

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. Your child should take Montelukast granules every evening.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

##### For children 6 months to 5 years of age:

The recommended dose is one sachet of Montelukast 4 mg granules to be taken by mouth each evening.

If your child is taking Montelukast granules, be sure that your child does not take any other products that contain the same active ingredient, montelukast.

For children 6 months to 2 years old, Montelukast 4 mg granules is available.  
For children 2 to 5 years old, Montelukast 4 mg chewable tablets and Montelukast 4 mg granules are available. The Montelukast 4 mg granules formulation is not recommended below 6 months of age.

## How should I give Montelukast 4 mg granules to my child?

This medicine is for oral use.

- Do not open the sachet until ready to use.
- Montelukast granules can be given either:
  - directly in the mouth;
  - OR mixed with a spoonful of cold or room temperature soft food (for example, apple sauce, ice cream, carrots and rice).
- Mix all of the contents of the Montelukast granules into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food.
- Be sure the child is given the entire spoonful of the granule/food mixture immediately (within 15 minutes). **IMPORTANT:** Never store any granule/food mixture for use at a later time.
- Montelukast granules is not intended to be dissolved in liquid. However, your child may take liquids after swallowing the Montelukast granules.
- Montelukast granules can be taken without regard to the timing of food intake.

## If your child takes more Montelukast granules 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 granules to your child

Try to give Montelukast granules as prescribed. However, if your child misses a dose, just resume the usual schedule of one sachet once daily. Do not give a double dose to make up for a forgotten dose.

## If your child stops taking Montelukast granules

Montelukast granules can treat your child's asthma only if he/she continues taking it. It is important for your child to continue taking Montelukast granules 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 granules, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast were:

- diarrhoea
- hyperactivity
- asthma
- scaly and itchy skin
- rash

Additionally, the following side effects were reported in clinical studies with either montelukast 10 mg film-coated tablets or montelukast 5 mg or 4 mg chewable tablets:

- abdominal pain
- headache
- thirst

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 with your child, which may be serious, and for which your child may need urgent medical treatment.

- Uncommon: 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
- 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
- rash
- fever
- elevated liver enzymes

Uncommon: 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: may affect up to 1 in 1000 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

- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering
- tender red lumps under the skin most commonly on your shins (erythema nodosum)

## Reporting of side effects

If your child gets 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 granules

### 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 sachet after EXP. The expiry date refers to the last day of that month.

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

Do not throw away any medicines via wastewater. 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 granules contains

- The active substance is montelukast. Each sachet of granules contains montelukast sodium which corresponds to 4 mg montelukast.
- The other ingredients are mannitol, hydroxypropyl cellulose, sodium laurilsulfate and magnesium stearate

### What Montelukast granules looks like and contents of the pack

Montelukast 4 mg granules are white to off-white granules.

Cartons of 7, 20, 28, 30 and 98 sachets. Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

### Manufacturer

Teva Operations Poland Sp. z o.o.  
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