

## MONTELUKAST 5 mg CHEWABLE TABLETS

For children 6 to 14 years of age  
montelukast

### Package leaflet: Information for the user

**Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you or your child.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your or your child's doctor or pharmacist.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's.
- If you or your child get any of the side effects, talk to your or your child's 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 Chewable Tablets is and what it is used for
2. What you need to know before you or your child take Montelukast Chewable Tablets
3. How to take Montelukast Chewable Tablets
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## 1 What Montelukast Chewable Tablets is and what it is used for

### What Montelukast Chewable Tablets is

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

### How Montelukast Chewable Tablets works

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

### When Montelukast Chewable Tablets should be used

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

- Montelukast Chewable Tablets is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.
- Montelukast Chewable Tablets may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 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 Chewable Tablets also helps prevent the narrowing of airways triggered by exercise.

Your or your child's doctor will determine how Montelukast Chewable Tablets should be used depending on the symptoms and severity of your or 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 you or your child take Montelukast Chewable Tablets

Tell your or your child's doctor about any medical problems or allergies you or your child have now or have had.

### Do not take/give Montelukast Chewable Tablets

- if you or your child 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 you or your child take Montelukast Chewable Tablets.

- If your or your child's asthma or breathing gets worse, tell your or your child's doctor immediately.
- Oral Montelukast Chewable Tablets is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. Always have your or your child's inhaled rescue medicine for asthma attacks with you.

- It is important that you or your child use all asthma medications prescribed by your doctor. Montelukast Chewable Tablets should not be used instead of other asthma medications your doctor has prescribed for you or your child.
- Any patient on anti-asthma medicines should 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 or your child's doctor.
- You or 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 your or your child's asthma worse.
- If you or your child have phenylketonuria you should note that Montelukast Chewable Tablets contains aspartame, which is a source of phenylalanine. The phenylalanine in the tablets may be harmful to people with phenylketonuria.

**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 Chewable Tablets, you should consult your or your child's doctor.**

### Children and adolescents

Do not give this medicine to children less than 6 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 Chewable Tablets

Tell your or your child's doctor or pharmacist if you or your child are taking/using, have recently taken/used or might take/use any other medicines, including those medicines obtained without a prescription.

Some medicines may affect how Montelukast Chewable Tablets works, or Montelukast Chewable Tablets may affect how other medicines work.

Tell your doctor if you or your child are taking the following medicines before starting Montelukast Chewable Tablets:

- 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 Chewable Tablets with food and drink

Montelukast Chewable tablets should not be taken immediately with food it should be taken at least 1 hour before or 2 hours after food.

### Pregnancy, breast-feeding and fertility

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 Chewable Tablets during this time.

#### Breast-feeding

It is not known if Montelukast Chewable Tablets appears in breast-milk. You should consult your doctor before taking Montelukast Chewable Tablets, if you are breast-feeding or intend to breast-feed.

### Driving and using machines

Montelukast Chewable Tablets is not expected to affect the 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 Chewable Tablets contains aspartame

This medicine contains 0.5 mg aspartame in each chewable tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### Montelukast Chewable Tablets contains sodium

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 Chewable Tablets

Always take or have your child take this medicine exactly as your or your child's doctor or

pharmacist has told you. Check with your or your child's doctor or pharmacist if you are not sure.

- You or your child should take only one chewable tablet of Montelukast Chewable Tablets once a day as prescribed by your doctor.
- It should be taken even when you or your child have no symptoms or have an acute asthma attack.

#### For children 6 to 14 years of age

The recommended dose is one 5 mg chewable tablet daily to be taken in the evening.

If you or your child are taking Montelukast Chewable Tablets, be sure that you or your child do not take any other medicines that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing. Montelukast Chewable Tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

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

For children 2 to 5 years of age, that have difficulty having the chewable tablet, a 4mg granule formulation is available.

For patients 15 years of age and older Montelukast Teva 10 mg Film-coated Tablets is available.

#### If you or your child take more Montelukast Chewable Tablets than you should

Contact your or 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 take Montelukast Chewable Tablets or give Montelukast Chewable Tablets to your child

Try to take/give Montelukast Chewable Tablets as prescribed. However, if you or your child miss a dose, just resume the usual schedule of one chewable tablet once daily.

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

#### If you or your child stop taking Montelukast Chewable Tablets

Montelukast Chewable Tablets can treat your or your child's asthma only if you or your child continue to take it.

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

If you have any further questions on the use of this medicine, ask your or 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 5 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast were:

- headache

Additionally, the following side effect was reported in clinical studies with Montelukast 10 mg film-coated tablets:

- abdominal pain

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 or 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
- 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 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

- 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 or your child 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 Chewable 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

Do not store above 25°C. Keep blister in the outer carton in order to protect from light.

Do not use this medicine if you notice visible signs of deterioration.

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 Chewable Tablets contains

- The active substance is montelukast. Each chewable tablet contains montelukast sodium (5.20 mg), which is equivalent to 5 mg montelukast.
- The other ingredients are: mannitol (E421), sodium laurilsulfate, hydroxypropyl cellulose, Red iron oxide (E172), Flav.cherry PHS-143671: (maltodextrins (maize) and starch modified E1450 (Waxy maize)), aspartame (E951), sodium starch glycolate Type A, magnesium stearate

#### What Montelukast Chewable Tablets looks like and contents of the pack

Montelukast 5 mg Chewable Tablets are mottled pink, square shaped tablets, debossed with "93" on one side and "7425" on the other side of the tablet.

Montelukast 5 mg Chewable Tablets is 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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