

Package leaflet: Information for the user

Montelukast Teva 4 mg Chewable Tablets

montelukast

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 child's 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 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 Teva Chewable Tablets is and what it is used for
2. What you need to know before your child takes Montelukast Teva Chewable Tablets
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1. What Montelukast Teva Chewable Tablets is and what it is used for

What Montelukast Teva Chewable Tablets is

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

How Montelukast Teva Chewable Tablets works

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

When Montelukast Teva Chewable Tablets should be used

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

- Montelukast Teva Chewable Tablets 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 Teva Chewable Tablets 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 Teva Chewable Tablets also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your child's doctor will determine how Montelukast Teva Chewable Tablets 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 Teva Chewable Tablets

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

Do not give Montelukast Teva Chewable Tablets 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 Teva Chewable Tablets to your child

- If your child's asthma or breathing gets worse, tell your child's doctor immediately.
- Oral Montelukast Teva Chewable Tablets 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 uses all asthma medications prescribed by your child's doctor. Montelukast Teva Chewable Tablets 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 child's 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.
- If your child has phenylketonuria you should note that Montelukast Teva 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 your child develops such symptoms while taking Montelukast Teva Chewable Tablets, 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 Teva Chewable Tablets

Tell your child's doctor or pharmacist if your child is taking/using, has recently taken/used or might be given any other medicines, including those medicines obtained without a prescription.

Some medicines may affect how Montelukast Teva Chewable Tablets works, or Montelukast Teva Chewable Tablets may affect how your child's other medicines work.

Tell your doctor if your child is taking the following medicines before starting Montelukast Teva 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 Teva Chewable Tablets with food and drink

Montelukast Teva 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

This subsection is not applicable for Montelukast Teva Chewable tablets since it is intended for use in children 2 to 5 years of age.

Driving and using machines

This subsection is not applicable for Montelukast Teva Chewable Tablets since it is intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

In adults Montelukast Teva Chewable Tablets is not expected to affect their 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 Teva 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 Teva 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 Teva Chewable Tablets

Always have your child take this medicine exactly as your child's 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 Teva 4 mg Chewable Tablets once a day as prescribed by his/her doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.

For children 2 to 5 years of age

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

If your child is taking Montelukast Teva Chewable Tablets, be sure that he/she does 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 Teva Chewable Tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

If your child takes more Montelukast Teva Chewable Tablets 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 Teva Chewable Tablets to your child

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

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

If your child stops taking Montelukast Teva Chewable Tablets

Montelukast Teva Chewable Tablets can treat your child's asthma only if he/she continues taking it. It is important for your child to continue taking Montelukast Teva Chewable Tablets for as long as your child's 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.

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

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

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 effects (may affect up to 1 in 10 people) thought to be related to montelukast 4 mg chewable tablets 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 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 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 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 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 Teva 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 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 Teva Chewable Tablets contains

- The active substance is montelukast sodium equivalent to 4 mg montelukast. Each chewable tablet contains montelukast sodium (4.16 mg), which is equivalent to 4 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 (maize) Type A, magnesium stearate

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

Montelukast Teva 4 mg Chewable Tablets are mottled pink, arc triangle shaped tablet, debossed with "93" on one side and "7424" on the other side of the tablet.

Montelukast Teva 4 mg Chewable Tablets is available in packs of 7, 14, 15, 20, 28, 30, 50, 56, 60, 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer(s)

1. TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary
2. Teva Operations Poland Sp. z o.o. Ul. Mogilska 80, 31-546 Kraków, Poland
3. Pharmachemie B.V., Swensweg 5, 2031GA Haarlem, The Netherlands

This medicine is authorised in the member states of the European Economic Area under the following names:

Austria: Montelukast Teva 4 mg Kautablette

Czech Republic: Montelukast Teva 4 mg, Žvýkáci tableta

Denmark: Montelukast Teva 4 mg Tyggetablet

Estonia: Montelukast Teva

Finland: Montelukast ratiopharm 4 mg purutabletti
Greece: Montelukast Teva 4 mg Chewable Tablet
Hungary: Montelukast Teva 4 mg Rágótabletta
Iceland: Montelukast Teva 4 mg tuggutöflur
Ireland: Montelukast Teva 4 mg Chewable Tablets
Norway: Montelukast Teva 4 mg, Tyggetablett
Poland: Montelukast Teva
Portugal: Montelucaste Teva Infantil
Slovakia: Montelukast Teva 4 mg
Spain: Montelukast Teva 4 mg comprimidos masticable EFG

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