

PACKAGE LEAFLET: INFORMATION FOR THE USER

MONTELUKAST TEVA 5 mg CHEWABLE TABLETS

montelukast

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 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 your or your child's.
- 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. 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 you or your child take Montelukast Teva Chewable Tablets**
- 3. How to take Montelukast Teva Chewable Tablets**
- 4. Possible side effects**
- 5. How to store Montelukast Teva Chewable Tablets**
- 6. Contents of the pack and other information**

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 is used

Your doctor has prescribed Montelukast Teva Chewable Tablets to treat asthma, preventing asthma symptoms during day and night.

- Montelukast Teva 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 Teva 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 Teva Chewable Tablets also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how Montelukast Teva 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 Teva Chewable Tablets

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

Do not take/give Montelukast Teva 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 Teva Chewable Tablets

- If your or your child's asthma or breathing gets worse, tell your 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 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 Teva 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 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 Teva Chewable Tablets contains aspartame, which is a source of phenylalanine. The phenylalanine in the tablets may be harmful to people with phenylketonuria.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with montelukast (see section 4). If you or your child develop such symptoms while taking Montelukast Teva 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 Teva Chewable Tablets

Tell your 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 Teva Chewable Tablets works, or Montelukast Teva Chewable Tablets may affect how other medicines work.

Tell your doctor if you or your child are 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 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 Teva Chewable Tablets during this time.

Breast-feeding

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

Driving and using machines

Montelukast Teva Chewable Tablets 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 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 take or have your child take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

- You or your child should take only one chewable tablet of Montelukast Teva 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 Teva 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 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 you or your child take more Montelukast Teva 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 Teva Chewable Tablets or give Montelukast Teva Chewable Tablets to your child

Try to take/give Montelukast Teva 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 Teva 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 Teva Chewable Tablets for as long as your 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 doctor or pharmacist.

For children 2 to 5 years old, Montelukast Teva 4 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 5 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelukast 5 mg chewable tablets 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
- 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 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 HPRC 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 ingredient is montelukast sodium 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 (maize) Type A, magnesium stearate

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

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

Montelukast Teva 5 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)

- TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary
- Teva Operations Poland Sp. z o.o. Ul. Mogilska 80, 31-546 Kraków, Poland
- TEVA UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, UK
- Pharmachemie B.V., Swensweg 5, 2031GA Haarlem, The Netherlands

This medicinal product is authorised in the member states of the EEA under the following names:

Austria: Montelukast ratiopharm 5 mg Kautablette

Czech Republic: Montelukast Teva 5 mg, Žvýkáci tableta

Denmark: Montelukast Teva 5 mg Tyggetablet

Estonia: Montelukast Teva

Finland: Montelukast ratiopharm 5 mg purutabletti

Greece: Montelukast Teva 5 mg Chewable Tablet

Hungary: Montelukast Teva 5 mg Rágótableta

Iceland: Montelukast Teva 5 mg tuggutöflur

Ireland: Montelukast Teva 5 mg Chewable Tablets

Norway: Montelukast Teva 5 mg, Tyggetablett

Poland: Montelukast Teva

Portugal: Montelucaste Teva Infantil

Slovakia: Montelukast Teva 5 mg

Spain: Montelukast Teva 5 mg comprimidos masticable EFG

This leaflet was last revised in: June 2021