

PACKAGE LEAFLET: INFORMATION FOR THE USER

MONTELUKAST TEVA 4 mg CHEWABLE TABLETS

montelukast

Read all of this leaflet carefully before you start taking this medicine 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.

In this leaflet

- 1. What Montelukast Teva Chewable Tablets is and what it is used for**
- 2. What you need to know before you 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

Montelukast Teva Chewable Tablets is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast Teva Chewable Tablets improves asthma symptoms and helps control asthma.

Your doctor has prescribed Montelukast Teva Chewable Tablets to treat your child's asthma, preventing asthma symptoms during 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 asthma medications 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 asthma symptoms which are triggered by exercise for patients 2 years of age and older.

Your 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 you take Montelukast Teva Chewable Tablets

Do not give Montelukast Teva Chewable Tablets

- if your child is allergic to montelukast sodium or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Montelukast Teva Chewable Tablets

- Oral Montelukast Teva Chewable Tablets is NOT intended for the treatment of a sudden attack of breathlessness. It will not help your child in this situation and should never be used for this purpose. If an attack occurs, the instructions that the doctor has given should be followed exactly. It is very important to have the medication needed for such an attack readily accessible at all times.
- If your child needs to use their beta-agonist inhaler more often than usual, you should consult your child's doctor as soon as possible.
- It is important that your child uses all the asthma medication prescribed by the doctor as intended. Montelukast Teva Chewable Tablets should not replace steroid medications (whether inhaled or taken by mouth) that your child may already be using.
- 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
- A rare condition has been seen in a very small number of patients taking asthma medications, including montelukast. If your child develops a combination of any of the following symptoms, particularly if they are persistent and worsening, seek medical attention immediately: flu-like illness, increasing breathlessness, pins and needles or numbness of limbs, and/or rash.
- Use in infants and toddlers: Montelukast Teva Chewable Tablets are not recommended for use in children under two years of age.

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 your child develops such symptoms while taking Montelukast Teva Chewable Tablets, you should consult your child's doctor.

Other medicines and Montelukast Teva Chewable Tablets

Montelukast Teva Chewable Tablets may be used together with other medicines your child may be taking for asthma. However, some medicines can interfere with Montelukast Teva Chewable Tablets, or Montelukast Teva Chewable Tablets may affect how your child's other medicines work.

Tell your doctor or pharmacist if your child is taking/using, has recently taken/used or might take/use any other medicines, including those medicines obtained without a prescription. This is particularly important if the other medicine is:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections).

Montelukast Teva Chewable Tablets with food and drink

If Montelukast Teva chewable tablets is taken together with food it should be taken in the evening 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

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.

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

Female patients who are pregnant, intend to become pregnant or think they might be pregnant should consult their doctor before taking Montelukast Teva Chewable Tablets.

Breast-feeding

It is not known whether Montelukast Teva Chewable Tablets is present in human breast-milk. The doctor should be consulted before Montelukast Teva Chewable Tablets is taken, if you are already breast feeding or intending to breast feed a baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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 that have been reported very rarely 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

Ensure that your child always takes Montelukast Teva Chewable Tablets exactly as your doctor or pharmacist has told you, even when your child has no symptoms, or if your child experiences an asthma attack. Check with your doctor or pharmacist if you are not sure.

The recommended dose for children aged 2 to 5 years is one Montelukast Teva 4 mg Chewable Tablet daily in the evening.

If Montelukast Teva Chewable Tablets use is associated with food, the tablets should be taken 1 hour before or two hours after food.

The safety and effectiveness of Montelukast Teva Chewable Tablets in children younger than 2 years old have not been established.

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.

If your child takes more Montelukast Teva Chewable Tablets than he/she should

If your child (or someone else) swallows a lot of the tablets all together, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause abdominal pain, sleepiness, thirst, headache, vomiting, and involuntary movement. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to give Montelukast Teva Chewable Tablets to your child

If your child misses a dose, just carry on with the next one as usual. Do not give your child a double dose to make up for a forgotten dose.

If your child stops taking Montelukast Chewable Tablets

It is important to continue taking Montelukast Teva Chewable Tablets in the presence or absence of symptoms, for as long as your child's doctor prescribes it, in order to help maintain control of your child's asthma. Montelukast Teva Chewable Tablets can help control your asthma only with continued use.

If you have any further questions on the use of this medicine, ask your 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.

Allergic reactions have also been reported which included swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, itching, rash or hives. It is vital that your child stops taking Montelukast Teva Chewable Tablets and that you seek immediate medical attention if your child experiences an allergic reaction.

The following side effects have been reported in clinical studies at the approximate frequencies shown:

Common: may affect up to 1 in 10 people
Abdominal pain, headache, thirst.

Additionally, while the medicine has been on the market, the following have been reported listed by frequency and starting with the most frequent:

Very common: may affect more than 1 in 10 people
upper respiratory infection (e.g. cold, sore throat),

Common: may affect up to 1 in 10 people
diarrhoea, nausea, vomiting; rash; fever; elevated levels of serum transaminases (liver enzymes)

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; dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression; dizziness, drowsiness, pins and needles/numbness, seizure; nosebleed; dry mouth, indigestion; bruising, itching, hives; joint or muscle pain, muscle cramps; tiredness, feeling unwell, swelling due to fluid retention

Rare: may affect up to 1 in 1,000 people
increased bleeding tendency, tremor, palpitations, angioedema (swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing)

Very rare: may affect up to 1 in 10,000 people
hallucinations, disorientation, suicidal thoughts and actions, stuttering, hepatitis (inflammation of the liver), tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning, hepatic eosinophilic infiltration

Very rare cases of a condition known as Churg-Strauss syndrome have been reported during montelukast treatment in asthmatic patients. You must tell your doctor right away if your child experiences a combination of any of the following symptoms, such as flu-like illness, increasing breathlessness, pins and needles or numbness of arms and legs, and/or rash, particularly if they are persistent or worsening.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 ingredient is montelukast sodium 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. TEVA UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, UK
4. 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 Teva 5mg Kautablette

Czech Republic: Montelukast Teva 5mg, Žvýkáci tableta

Denmark: Montelukast Teva 5mg Tyggetablet

Estonia: Montelukast Teva

Finland: Montelukast ratiopharm 4 mg purutabletti

Greece: Montelukast Teva 5mg Chewable Tablet
Hungary: Montelukast Teva 5mg Rágótabletta
Iceland: Montelukast Teva 5mg tuggutöflur
Ireland: Montelukast Teva 5 mg Chewable Tablets
Norway: Montelukast Teva 5mg, Tyggetablett
Poland: Montelukast Teva
Portugal: Montelucaste Teva Infantil
Slovakia: Montelukast Teva 5mg
Spain: Montelukast Teva 5mg comprimidos masticable EFG

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