

Package Leaflet: Information for the user

Montelukast Paediatric 4mg chewable tablets

(Montelukast)

For children from 2 to 5 years of age

Read all of this leaflet carefully before your child 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, pharmacist or nurse.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This include any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Montelukast is and what it is used for
2. What you need to know before you take Montelukast
3. How to take Montelukast
4. Possible side effects
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1. What Montelukast is and what it is used for

The full name of this medicine is Montelukast Paediatric 4mg chewable tablets (referred to as Montelukast in the rest of this leaflet).

Montelukast Paediatric 4mg chewable tablets contains the active substance montelukast.

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. By blocking leukotrienes, montelukast improve asthma symptoms and help control asthma.

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

- Montelukast 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 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 also help prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your child's doctor will determine how Montelukast 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

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

Do not give Montelukast:

- If your child 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, pharmacist or nurse before giving him/her Montelukast:

- If your child's asthma or breathing gets worse, tell your child's doctor immediately.
- Montelukast is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your child's 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 child's doctor. Montelukast 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 (lung) symptoms, and or rash, you should consult your child's doctor.
- Your child should not take acetylsalicylic 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 you develop such symptoms while taking montelukast, you should contact your doctor.

Children and adolescents

Do not give this medicine to children less than 2 years 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

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might take other medicines including those obtained without prescription.

Some medicines may affect how Montelukast chewable tablets work, or Montelukast chewable tablets may affect how your child's other medicines work.

It is especially important to tell your child's doctor if your child is taking the following medicines before starting Montelukast:

- **phenobarbital** (used for treatment of epilepsy)
- **phenytoin** (used for treatment of epilepsy)
- **rifampicin** (used to treat tuberculosis and some other infections)
- **gemfibrozil** (used for treatment of high lipid levels in plasma)

Montelukast with food, drink and alcohol

Montelukast Paediatric 4mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food. (See also section 3. How to take Montelukast)

Pregnancy, breast-feeding and fertility

This sub section is not applicable for the Montelukast Paediatric 4mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Use in Pregnancy

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 Montelukast. Your doctor will assess whether you can take Montelukast during this time.

Use in breast-feeding

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

Driving and using machines

This subsection is not applicable for the Montelukast Paediatric 4mg chewable tablets since they are intended for use in children 2 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 a car or operate machinery. 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 patient's ability to drive or operate machinery.

Montelukast contains Aspartame

Montelukast chewable tablets contain aspartame, a source of phenylalanine, which may be harmful for people with phenylketonuria. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each Montelukast Paediatric 4mg chewable tablets contains phenylalanine (equivalent to 0.539mg phenylalanine per 4mg chewable tablets).

Information on sodium content:

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

3. How to take Montelukast

Always give 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. For children who have problems consuming chewable tablets, oral granule formulation is available from other company.

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- Your child should take only one tablet of Montelukast once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.
- To be taken by mouth. The tablets are to be chewed before swallowing. If swallowed, it should be taken with a sufficient amount of fluid (for example with a glass of water).

For children 2 to 5 years of age:

One 4 mg chewable tablet daily to be taken in the evening. Montelukast

Paediatric 4 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food. The tablets are to be chewed before swallowing. If your child is taking Montelukast, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

For children 2 to 5 years old, Montelukast Paediatric 4mg chewable tablets are available.

For children 6 to 14 years old, Montelukast Paediatric 5mg chewable tablets are available. The Montelukast Paediatric 4mg chewable tablets are not recommended below 2 years of age.

If your child takes more Montelukast 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 to your child

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

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

If your child stops taking Montelukast

Montelukast can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking Montelukast for as long as your child's doctor prescribes. They 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, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies with Montelukast Paediatric 4 mg chewable tablets, the most commonly reported side effects (occurring in more than 1 in 10 people) thought to be related to Montelukast 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, which may be serious, and for which you may need urgent medical treatment.

Uncommon: the following 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: the following may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: the following 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)

Additionally, while the medicine has been on the market, the following side effects have been reported:

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 enzyme

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)

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

In asthmatic patients treated with montelukast, very rare cases of a 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) have been reported. You must tell your doctor right away if your child gets one or more of these symptoms.

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 the Yellow Card Scheme at: 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

- 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 carton and blister (EXP). The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package in order to protect from light and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other Information

What Montelukast contains

- The active substance is montelukast. Each tablet contains 4.16mg montelukast sodium which corresponds to 4mg of montelukast.
- The other ingredients are: Mannitol (E421), microcrystalline cellulose, red ferric oxide (E172), croscarmellose sodium, cherry flavour, aspartame (E951), and magnesium stearate, hydroxy propyl cellulose (E463).

What Montelukast look like and contents of the pack

Chewable tablets

Montelukast chewable tablets are pink coloured, oval, bi-convex tablets, debossed with 'BL 4' on one side and plain on other side.

Blister pack: Aluminium/Aluminium Blister Pack size: 28, 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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