

FLAT DIMENSION = 130 x 470mm
FOLDED DIMENSION = 130 x 29mm

5mm

5mm

30 mm

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
5. How to store Montelukast
6. Contents of the pack and other information

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 flulike 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). There have also been reports of these symptoms continuing after treatment is stopped. If you develop such symptoms while taking montelukast or if these symptoms do not resolve after montelukast is stopped, you should contact your prescriber.

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 breastfeeding 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

