

Package leaflet: Information for the user

Montelukast Paediatric 4 mg chewable tablets

montelukast

Read all of this leaflet carefully before your child starts 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, please 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 Paediatric is and what it is used for
2. What you need to know before your child takes Montelukast Paediatric
3. How to take Montelukast Paediatric
4. Possible side effects
5. How to store Montelukast Paediatric
6. Contents of the pack and other information

1. What Montelukast Paediatric is and what it is used for

Montelukast Paediatric contains the active substance montelukast. Montelukast Paediatric is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast Paediatric improves asthma symptoms and helps control asthma.

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

- Montelukast Paediatric 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 Paediatric 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 Paediatric 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 Paediatric 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 Paediatric

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

Do not give Montelukast Paediatric to your child if he/she

- is allergic (hypersensitive) to montelukast or any of the other ingredients of Montelukast Paediatric (listed in section 6).

Warnings and precautions

Talk to your child's doctors or pharmacist before your child takes Montelukast Paediatric.

Take special care with Montelukast Paediatric

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast Paediatric 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 Paediatric should not be used instead of other asthma medications your child's 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.

Children

Montelukast Paediatric should not be prescribed to children below 2 years of age because safety and effectiveness in children have not been established

Other medicines and Montelukast Paediatric

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

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

Tell your child's doctor if your child is taking the following medicines before starting Montelukast Paediatric:

- Phenobarbital (used for treatment of epilepsy)
- Phenytoin (used for treatment of epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections)

Montelukast Paediatric with food

Montelukast Paediatric 4 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

This subsection is not applicable for the Montelukast Paediatric 4 mg 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.

Pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montelukast Paediatric. Your doctor will assess whether you can take Montelukast Paediatric during this time.

Breast-feeding

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

Driving and using machines

This subsection is not applicable for the Montelukast Paediatric 4 mg 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 Paediatric 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 patients' ability to drive or operate machinery.

Montelukast Paediatric contains aspartame

Montelukast Paediatric chewable tablets contain aspartame, a source of phenylalanine. May be harmful for people with phenylketonuria.

3. How to take Montelukast Paediatric

- This medicine is to be given to a child under adult supervision.
- Your child should take only one tablet of Montelukast Paediatric 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.

- Always take Montelukast Paediatric exactly as your child's doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.
- To be taken by mouth

Use in children and adolescents

For children 2 to 5 years of age:

One Montelukast Paediatric 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.

If your child is taking Montelukast Paediatric, 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 4 mg chewable tablets are available.

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

If your child takes more Montelukast Paediatric 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 Paediatric to your child

Try to give Montelukast Paediatric 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 Paediatric

Montelukast Paediatric can treat your child's asthma only if your child continues taking it.

It is important for your child to continue taking Montelukast Paediatric for as long as your 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.

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 at least 1 of 100 patients and less than 1 of 10 paediatric patients treated) thought to be related to Montelukast Paediatric 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).

Additionally, while the medicine has been on the market, the following 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
- rash
- fever

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 [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

Rare: may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations
- disturbance in attention
- memory impairment
- Serious allergic reaction which causes swelling of the face or throat

Very rare: may affect up to 1 in 10,000 people

- behaviour and mood related changes [hallucinations, disorientation, suicidal thoughts and actions]
- hepatitis (inflammation of the liver)

- tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reaction (erythema multiforme) that may occur without warning
- Coughing, wheezing, shortness of breath and a high temperature, which are symptoms of inflammation of the lungs associated with an increase in white blood cells (pulmonary eosinophilia)

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Montelukast Paediatric

- 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 label / carton/ blister. The expiry date refers to the last day of that month.
- 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 protect the environment.

6. Contents of the pack and other information

What Montelukast Paediatric contains

- The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 4 milligram of montelukast.
- The other ingredients are: Mannitol, microcrystalline cellulose, hydroxypropyl cellulose (E 463), red iron oxide (E 172), croscarmellose sodium, cherry flavour (contains maltodextrin (Maize), nature identical flavouring substance, acacia gum (E 414), propylene glycol, flavouring preparation and natural flavouring substance), aspartame (E951), and magnesium stearate.

What Montelukast Paediatric looks like and contents of the pack

Montelukast Paediatric 4 mg chewable tablets are pink coloured, oval shaped, biconvex, uncoated chewable tablets that are plain on both sides.

Blisters in packages of: 10, 14, 28, 56 and 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Cipla (EU) Limited, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom

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