Montelukast 5 mg chewable tablets
For children from 6 to 14 years

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1. WHAT MONTELUKAST IS AND WHAT IT IS USED FOR
Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast improves asthma symptoms and helps control asthma.

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

• Montelukast 5 mg chewable tablets are used for the treatment of 6 to 14 year old patients who are not adequately controlled on their medication and need additional therapy.
• Montelukast 5 mg 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 5 mg chewable tablets also help prevent the narrowing of airways triggered by exercise for 6 year old patients and older.

Your 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:
• coughing, wheezing, tightness in the chest, and chest tightness.
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Asthma includes:
• coughing, wheezing, tightness in the chest, and chest tightness.

2. WHAT YOU NEED TO KNOW BEFORE YOU GIVE MONTELUKAST TO YOUR CHILD
Tell your doctor about any medical problems or allergies your child has now or has had.

Do not give Montelukast to your child:
 If your child is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Tell your doctor or pharmacist before giving Montelukast to your child:
• If your child’s asthma or breathing gets worse, tell your doctor immediately.
• Oral Montelukast is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your child’s inhaled rescue medicine for asthma attacks with you.

• It is important that your child uses all the asthma medication prescribed by the doctor. Montelukast 5 mg chewable tablets should not be used instead of other asthma medications your doctor has prescribed to your child.
• If your child is an anti-asthma medications, be aware that if he/she develops a combination of symptoms such as flu-like illness, pain and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your 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.

Other medicines and Montelukast
Some medicines may affect how Montelukast works, or Montelukast may affect how your child’s other medicines work.

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

Tell the 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 infections).

Montelukast with food
Montelukast 5 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
Pregnancy
This subsection is not applicable for the Montelukast 5 mg chewable tablets since they are intended for use in children from 6 to 14 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. Your doctor will assess whether you can take Montelukast during this time.

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
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 patients’ ability to drive or operate machinery.

Montelukast contains aspartame
Contains a source of phenylalanine. May be harmful for children with phenylketonuria.

3. HOW TO TAKE MONTELUKAST
This medicine is to be given to a child under adult supervision.
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 has an acute asthma attack. Always take your child's medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

To be taken by mouth

Use in children 6 to 14 years of age

One 5 mg chewable tablet daily to be taken in the evening. Montelukast 5 mg chewable tablets should not be taken immediately with food; they should be taken at least 1 hour before or 2 hours after food. If your child is taking montelukast, be sure that he/she does not take any other medicine that contains the same active ingredient, montelukast.

For children 2 to 5 years old, Montelukast 4 mg chewable tablets are available. For children of this age group who have difficulties consuming chewable tablets, a 4 mg granule formulation is available. For children 6 to 14 years old, Montelukast 5 mg chewable tablets are available. The Montelukast 4 mg or 5 mg chewable tablets are not recommended below 2 years of age.

If your child takes more Montelukast than he/she should

Contact your 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 you or 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 you or your child continues to take it. It is important to continue taking montelukast 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 doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

In clinical studies with montelukast 4 mg chewable tablets, the most commonly reported side effect (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to treatment with montelukast were:

Abdominal pain

Thirst

In clinical studies with montelukast 5 mg chewable tablets, the most commonly reported side effect (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to treatment with montelukast was:

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 with the same frequency in patients treated with montelukast or placebo tablets (that do not contain any active substance).

The frequency of possible side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

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

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

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

• upper respiratory infection (very common)
• increased bleeding tendency (rare)
• allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (uncommon)
• behaviour and mood related changes (dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression [uncommon], tremor [Rare], hallucination, disinclination, sexual thoughts and actions [Very rare])

• dizziness, drowsiness, pins and needles/numbness (uncommon)
• palpitations (Rare)
• nose bleed (uncommon)
• dizziness, nausea, vomiting (Common) [dry mouth, indigestion (uncommon)]
• hepatitis (inflammation of the liver) (very rare)
• rash (Common); bruising, itching, hives (uncommon); tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reaction (erythema multiforme), which may occur without warning (very rare)
• joint or muscle pain, muscle cramps (uncommon)
• fever (Common); tiredness, feeling unwell, swelling (uncommon)

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illnesses, 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 or your child gets 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. 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 blister and carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

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 chewable tablets contain

• The active substance is montelukast.

Each chewable tablet contains 5 mg montelukast (as montelukast sodium).

• The other ingredients are mannitol (E421), microcrystalline cellulose, rosaniline hydrochloride, hypromellose, aspartame (E951), red iron oxide (E172), flavour cherry black (also contains glycerol triacetate [E1513]) and magnesium stearate (see section 2).

What Montelukast chewable tablets looks like and contains

Pink, markings, round, slightly biconvex tablets with bevelled edges and inscription 5 on one side.

Boxes of 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140 or 200 chewable tablets in blisters are available.

Marketing Authorisation Holder

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