Package leaflet: Information for the user

P4005T

Pharmacode

MONTELUKAST 5mg CHEWABLE TABLETS

Montelukast

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you or your child.
- 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 you or 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 or your child's.
- If you or your child get any side effects, talk to your 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 5mg chewable tablet is and what it is used for
2. What you need to know before you take Montelukast 5mg chewable tablet
3. How to take Montelukast 5mg chewable tablet
4. Possible side effects
5. How to store Montelukast 5mg chewable tablet
6. Contents of the pack and other information

1. What Montelukast 5mg chewable tablet is and what it is used for

What Montelukast 5mg chewable tablet is
Montelukast 5mg chewable tablet is a leukotriene receptor antagonist that blocks substances called leukotrienes.

How Montelukast 5mg chewable tablet works
Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast 5mg chewable tablet improves asthma symptoms and helps control asthma.

When Montelukast 5mg chewable tablet should be used
Your doctor has prescribed Montelukast 5mg chewable tablet to treat asthma, preventing your asthma symptoms during the day and night.
- Montelukast 5mg chewable tablet is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled ontheir medication and need additional therapy.
- Montelukast 5mg chewable tablet 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 5mg chewable tablet also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how Montelukast 5mg chewable tablet should be used depending on the symptoms and severity of your or 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 5mg chewable tablet

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

Do not take Montelukast 5mg chewable tablet
- if you or 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 doctor or pharmacist before you or your child take Montelukast 5mg chewable tablet.
- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast 5mg chewable tablet is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you or your child. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. Montelukast 5mg chewable tablet should not be used instead of other asthma medications your doctor has prescribed for you or your child.
- Any patient on anti-asthma medicines should be aware that if you develop 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 doctor.
- You or 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 your 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 your child develop such symptoms while taking montelukast 5 mg chewable tablet, or if these symptoms do not resolve after montelukast is stopped, you should consult your prescriber.

Children and adolescents
Do not give this medicine to children less than 6 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 5mg chewable tablet
Tell your doctor or pharmacist if you or your child are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Some medicines may affect how Montelukast 5mg chewable tablet works, or Montelukast 5mg chewable tablet may affect how other medicines work.

Tell your doctor if you or your child is taking the following medicines before starting Montelukast 5mg chewable tablet:
- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)

Montelukast 5mg chewable tablet with food and drink
Montelukast 5mg chewable tablet should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding
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 5mg chewable tablet.

Pregnancy
Your doctor will assess whether you can take Montelukast 5mg chewable tablet during this time.

Breast-feeding
It is not known if Montelukast 5mg chewable tablet appears in breast milk. You should consult your doctor before taking Montelukast 5mg chewable tablet if you are breast-feeding or intend to breast-feed.

Driving and using machines
Montelukast 5mg chewable tablet 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 with Montelukast 5mg chewable tablet may affect some patients' ability to drive or operate machinery.

Montelukast 5mg chewable tablet 5mg chewable tablets contain aspartame and sodium
This medicine contains 1.5mg aspartame in each 5mg chewable tablet which is equivalent to 0.842mg phenylalanine. Aspartame is a source of phenylalanine. It may be harmful if you or your child have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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

3. How to take Montelukast 5mg chewable tablet

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.
- You or your child should take only one chewable tablet of Montelukast 5mg chewable tablet once a day as prescribed by your doctor.
- It should be taken even when you or your child has no symptoms or has an acute asthma attack.

For children 6 to 14 years of age:
The recommended dose is one 5mg chewable tablet daily to be taken in the evening.

500.00 mm

180.00 mm

Crescent PHARMA LIMITED

Product:	Montelukast 5mg Chewable Tablets - Uni Medico
Item Code:	P4005T
Size:	180 x 500 mm
Min. Point size:	10pt
O. Artwork	29/05/26
Proof No.	1
Amendment Date	

Colours Used	
	Process black
	Keyline - Does not print

Pharmacode

If you or your child are taking Montelukast 5mg chewable tablet, be sure that you or your child do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

The tablets are to be chewed before swallowing.

Montelukast 5mg Chewable Tablet should not be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

If you or your child takes more Montelukast 5mg chewable tablet than you 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 take Montelukast 5mg chewable tablet or give Montelukast 5mg chewable tablet to your child
Try to take Montelukast 5 mg chewable tablet as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

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

If you or your child stops taking Montelukast 5mg chewable tablet
Montelukast 5mg chewable tablet can treat you or your child's asthma only if you or your child continues to take it.

It is important to continue taking Montelukast 5mg chewable tablet for as long as your doctor prescribes. It will help control you or your child's asthma.

If you have any further questions on the use of t his medicine, ask your 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 5mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelukast 5 mg chewable tablets were:
- headache

Additionally, the following side effect was reported in clinical studies with Montelukast 10mg film-coated tablets:
- abdominal pain

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 or your child 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)

Other side effects while the medicine has been on the market
Very common: the following may affect more than 1 in 10 people
- upper respiratory infection

Common: the following may affect up to 1 in 10 people
- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon: the following 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: the following may affect up to 1 in 1,000 people
- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following 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

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 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 5mg chewable tablet

- 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 after EXP. The first two numbers indicate the month; the last four numbers indicate the year. The expiry date refers to the last date of that month.
- This medicinal product does not require any special storage conditions.
- 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 5mg chewable tablet contains
- The active substance is montelukast. Each chewable tablet contains montelukast sodium which corresponds to 5mg of montelukast.
- The other ingredients are: Mannitol (E421), microcrystalline cellulose, hydroxypropyl cellulose, Ferric oxide red (E172), croscarmellose sodium, cherry flavour, aspartame (E951), and magnesium stearate.

What Montelukast 5mg chewable tablet looks like and contents of the pack
Montelukast 5mg chewable tablets are Light pink to pink coloured, speckled, round, biconvex shaped, chewable tablets, debossed with 'I' on one side and "113" on the other side.
Dimension: 9.5 mm

Blisters in packages of: 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140, and 200 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Crescent Pharma Ltd., Key House,
Sarum Hill, Basingstoke, RG21 8SR, UK.

This package leaflet was last revised in June 2026.

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