

Package leaflet: Information for the patient

Montelukast Mylan 4 mg Chewable Tablets

montelukast

For children 2 to 5 years old

Read all of this leaflet carefully before you 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 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 yours or your child's.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Montelukast Mylan 4 mg is and what it is used for
2. What you need to know before you give Montelukast Mylan 4 mg
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1. What Montelukast Mylan 4 mg is and what it is used for

Montelukast Mylan 4 mg contains montelukast, which is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. By blocking leukotrienes, Montelukast Mylan 4 mg improves asthma symptoms and helps control asthma.

Your doctor has prescribed Montelukast Mylan 4 mg to treat your child's asthma, preventing asthma symptoms during the day and night.

- Montelukast Mylan 4 mg 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 Mylan 4 mg 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 Mylan 4 mg also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Montelukast Mylan 4 mg 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 give Montelukast Mylan 4 mg

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

Do not give Montelukast Mylan 4 mg to your child if he/she:

- is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Montelukast Mylan 4 mg is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you. Talk to your doctor if you or your child needs more inhaled rescue medicine than usual for the acute asthma attacks.
- It is important that your child take all asthma medications prescribed by your doctor. Montelukast Mylan 4 mg 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 (lung) 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.
- Patients should be aware that various neuropsychiatric events (for example behavior and mood related changes) have been reported in adults, adolescents and children with montelukast (see section 4). If your child develops such symptoms while taking Montelukast Mylan 4 mg, you should consult your child's doctor.

Children and adolescents

Do not give this medicine to children less than 2 years of age.

For children 2 to 5 years old, Montelukast Mylan 4 mg may be available.

For children 6 to 14 years old, Montelukast Mylan 5 mg may be available.

Other medicines and Montelukast Mylan 4 mg

Some medicines may affect how Montelukast Mylan 4 mg works, or Montelukast Mylan 4 mg 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, including those obtained without a prescription.

Tell your doctor if your child is taking the following medicines before starting Montelukast Mylan 4 mg

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

Pregnancy and breast-feeding

This subsection is not applicable for the Montelukast Mylan 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.

Use in pregnancy

If you are pregnant, 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.

Use in breast-feeding

It is not known if montelukast appears in breast milk. You should talk to your doctor before taking Montelukast Mylan 4 mg if you are breast-feeding or intend to breast-feed.

Driving and using machines

This subsection is not applicable for the Montelukast Mylan 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 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 tablets may affect some patients' ability to drive or operate machinery.

Montelukast Mylan 4 mg contains aspartame and sodium

This medicine contains 2 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. If your child has PKU you should take into account that each 4 mg tablet contains phenylalanine (equivalent to 1.12 mg phenylalanine per chewable tablet). This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to give Montelukast Mylan 4 mg

Always give this medicine to your child exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- This medicine is to be given to a child under adult supervision.
- Your child should take only one tablet of Montelukast Mylan 4 mg once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or he/she has an acute asthma attack.
- To be taken by mouth.

For children 2 to 5 years of age:

The recommended dose is one 4 mg chewable tablet daily to be taken in the evening. Montelukast Mylan 4 mg 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 Mylan 4 mg, be sure that he/she does not take any other products that contain the same active ingredient, montelukast.

If your child takes more Montelukast Mylan 4 mg 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, being sick (vomiting), and hyperactivity.

If you forget to give Montelukast Mylan 4 mg to your child

Try to take Montelukast Mylan 4 mg as prescribed. However, if your child misses a dose, just resume the usual schedule of one tablet once daily.

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

If your child stops taking Montelukast Mylan 4 mg

Montelukast Mylan 4 mg can treat your child's asthma only if he/she continues to take it.

It is important for your child to continue taking Montelukast Mylan 4 mg 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.

If your child gets any of the following side effects they should stop taking this medicine and see their doctor immediately or go to the nearest hospital casualty department straight away:

Uncommon (may affect up to 1 in 100 people)

- Severe allergic reaction (called anaphylaxis) that may include difficulty in breathing, dizziness and collapse
- Seizure (fits)

Rare (may affect up to 1 in 1,000 people)

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)

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

- Yellowing of the skin or eyes which may be caused by hepatitis (inflammation of the liver) or liver problems (hepatic eosinophilic infiltration)
- Suicidal thoughts and actions
- Chest pain with a dry cough, fever, shortness of breath and wheezing due to an inflammation of the lungs caused by an increase in the numbers of a type of white blood cell (pulmonary eosinophilia)
- Severe skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) called erythema multiforme

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 lung (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.

In clinical studies with montelukast 4 mg chewable tablets, the most commonly reported side effects (occurring in up to 1 in 10 children) thought to be related to montelukast chewable tablets were:

- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with montelukast 10 mg film-coated tablets and montelukast 5 mg chewable tablets:

- headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast tablets 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
- feeling sick (nausea)
- being sick (vomiting)
- rash
- raised liver enzymes, which show up in test results
- fever

Uncommon (may affect up to 1 in 100 people)

- Behaviour and mood related changes e.g. 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
- Nosebleed
- Dry mouth
- Indigestion
- Bruising, itching, hives
- Joint or muscle pain, muscle cramps
- Tiredness, feeling unwell
- Swelling
- Bedwetting in children

Rare (may affect up to 1 in 1,000 people)

- Increased bleeding tendency
- Shaking (tremor)
- Disturbance in attention
- Memory impairment
- Uncontrolled muscle movement
- Fast or irregular heartbeats (palpitations)

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

- Hallucinations (seeing, feeling or hearing things that are not there), disorientation
- Tender red lumps under the skin most commonly on your shins (erythema nodosum)
- Obsessive-compulsive symptoms
- Stuttering
- Reduction in blood platelets that increases the risk of bruising or bleeding more easily or for longer than usual

Reporting of side effects

If 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 HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Montelukast Mylan 4 mg

- 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 or bottle or blister after "EXP". The expiry date refers to the last day of that month.
- Bottles: Once open use within 100 days.
- 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 Mylan 4 mg contains

- The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 4 mg of montelukast.
- The other ingredient(s) are:

mannitol,
microcrystalline cellulose,
croscarmellose sodium,
magnesium stearate,
sodium laurilsulfate,
colloidal anhydrous silica,
aspartame (E951) (see section 2 “Montelukast Mylan 4 mg contains aspartame”),
cherry flavour (maize maltodextrin, benzyl alcohol (E1519), triethyl citrate (E1505))

What Montelukast Mylan 4 mg looks like and contents of the pack

White to off-white, oval, tablets with sides that curve outwards, marked with “M” on one side and “MS1” on the other side.

Tablets are available in the following pack types and sizes:

Blister packs in sizes of 7, 10, 14, 20, 28, 30, 50, 56, 98, 100, 112 or 200 tablets or in perforated unit dose blisters of 28 x 1.

White plastic bottles with white non see-through plastic cap containing absorbent cotton and a desiccant canister (do not eat the desiccant) in pack sizes of 28, 56, 100, 112, 200 & 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer(s)

McDermott Laboratories Ltd t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft, H-2900 Komárom Mylan utca 1, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Montelukast Mylan 4 mg žvýkácí tablety
Germany	Montelukast Mylan 4 mg Kautabletten
Ireland	Montelukast Mylan 4 mg chewable tablets
Italy	Montelukast Mylan
Malta	Montelukast Mylan 4 mg
Portugal	Montelucaste Mylan
Spain	Montelukast Mylan 4 mg comprimidos masticables EFG
United Kingdom (NI)	Montelukast 4 mg chewable tablets

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