Package leaflet: Information for the patient

Montelukast Paediatric 5 mg chewable tablets
For children 6 to 14 years of age

Montelukast

Read all of this leaflet carefully before you or 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, please 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 gets 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 Paediatric is and what it is used for
2. What you need to know before you or your child take 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. Montelukast Paediatric ActavisWhat Montelukast Paediatric is and what it is used for

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

- Montelukast Paediatric is used for the treatment of 6 to 14 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 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 Paediatric also helps prevent the narrowing of airways triggered by exercise for patients 6 to 14 years of age.

Your or your child's doctor will determine how Montelukast Paediatric should be used depending on the symptoms and severity of your or your child's asthma.

## 2. What you need to know before you or your child take Montelukast Paediatric

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

Do not use Montelukast Paediatric

- 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 or your child‘s doctor, pharmacist or nurse before using Montelukast Paediatric
- If your or your child’s asthma or breathing gets worse, tell your or your child’s doctor immediately.
- Oral Montelukast Paediatric 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 or your child’s inhaled rescue medicine for asthma attacks with you/him/her.
- It is important that you or your child take all asthma medications prescribed by your or your child’s doctor.
  Montelukast Paediatric should not be used instead of other asthma medications your or your child’s doctor has prescribed for you/him/her.
- If you or your child is on anti-asthma medicines, be aware that if you or 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 or your child’s doctor.
- You or your child should not take acetyl-salicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs) if they make your or his/her asthma worse.

Patients should be aware that various neuropsychiatric events (for example behaviour 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 Paediatric, you should consult your child’s doctor.

Other medicines and Montelukast Paediatric

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

Please tell your or your child’s doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines.

Tell your doctor if you or 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)
- gemfibrozil (used for treatment of high lipid levels in plasma)

Montelukast Paediatric with food and drink

Montelukast Paediatric 5 mg chewable tablets should not be taken immediately with food; they should be taken at least one hour before or two hours after food.

Pregnancy and breast-feeding

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.

Breast-feeding

It is not known if Montelukast Paediatric appears in breast milk. You should consult your doctor before taking Montelukast Paediatric if you are breast-feeding or intend to breast-feed. Your doctor will assess whether you can take Montelukast Paediatric during this time.

Driving and using machines

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 Paediatric may affect some patients' ability to drive or operate machinery.

Montelukast Paediatric chewable tablets contain aspartame, a source of phenylalanine (an amino acid). May be harmful for people with phenylketonuria (a genetic disorder affecting the metabolism).

Montelukast Paediatric chewable tablets contain lactose. If you have been told by your or your child's doctor that you/he/she has an intolerance to some sugars, contact your/his/her doctor before this medicinal product is taken.

## 3. How to take Montelukast Paediatric

- Always use this medicine exactly as your or your child's doctor has told you/him/her. Check with your or your child's doctor or pharmacist if you are not sure.
- The recommended dose is one tablet of Montelukast Paediatric once a day as prescribed by your or your child's doctor.
- It should be taken even when you or your child has no symptoms or if you or your child has an acute asthma attack.
- To be taken by mouth.

For children 6 to 14 years of age:
One Montelukast Paediatric 5 mg chewable tablet daily to be taken in the evening. Montelukast Paediatric Actavis 5 mg chewable tablets should not be taken immediately with food; it should be taken at least one hour before or two hours after food.

If you or your child is taking Montelukast Paediatric, be sure that you or your child does not take any other medicines that contain the same active ingredient, montelukast.

For other age groups:
For other age groups, other strengths and pharmaceutical forms of montelukast may be available.

If you or your child takes more Montelukast Paediatric than you/he/she should

Contact your or 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 take Montelukast Paediatric or give Montelukast Paediatric to your child

Try to take/give Montelukast Paediatric as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet once daily.

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

If you or your child stops taking Montelukast Paediatric
Montelukast Paediatric can treat your or your child's asthma only if you or your child continues taking it.

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

If you have any further questions on the use of this product, ask your or 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 you notice any of the following serious side effects that have been reported with montelukast, stop using Montelukast Paediatric and contact a doctor immediately:

- sudden wheezing, swelling of lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction). This side effect is uncommon (may affect up to 1 in 100 people).
- flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome). This side effect is very rare (may affect up to 1 in 10,000 people).
- suicidal thoughts and actions. This side effect is very rare (may affect up to 1 in 10,000 people).
- severe skin reactions (erythema multiforme) that may occur without warning. This side effect is very rare (may affect up to 1 in 10,000 people).

The following side effects have also been reported with montelukast:

Very common: may affect more than 1 in 10 people

- Colds (upper respiratory infection)

Common: may affect up to 1 in 10 people

- Headache
- Abdominal pain
- Thirst
- Diarrhoea, nausea, vomiting
- Rash
- Fever
- Asthma
- Hyperactivity
- Red, itchy skin (eczema)
- Increased amounts of certain substances in the blood (transaminases)

Uncommon: may affect up to 1 in 100 people

- 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, seizures (fits)
- 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

- Tremor, disturbance in attention, memory impairment
- Increased bleeding tendency

- Shaking
- Feeling your heartbeat (palpitations)
- Swelling of the skin

Very rare: may affect up to 1 in 10,000 people
- Hallucinations, confusion, stuttering
- Hepatitis (inflammation of the liver), liver problems (hepatic eosinophilic infiltration)
- Tender red lumps under the skin most commonly on your shins (erythema nodosum)

Reporting of side effects
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. 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 carton and blister after EXP. 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 store above 30°C.
- 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 chewable tablet contains montelukast sodium which corresponds to 5 mg of montelukast.
- The other ingredients (excipients) are: microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, lactose monohydrate, iron oxide red (E172), mannitol, silarom cherry flavour (nature-identical flavouring substances, flavouring preparations, natural flavouring substances, maltodextrin (potato), gum arabic (acacia) (E414), triacetin (E1518), ethyl maltol, maltol, alpha-tocopherol (E307)), aspartame (E951), magnesium stearate.

What Montelukast Paediatric looks like and contents of the pack

5 mg Montelukast Paediatric chewable tablets are pink, mottled, round, biconvex tablets with M5 engraved on one side.

Blisters in packages of:
10, 14, 20, 28, 30, 50, 56, 100 chewable tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Actavis Limited
BLB016 Bulebel Industrial Estate
Zejtun ZTN 3000
Malta

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

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|---|---|
| Ireland | Montelukast Paediatric 5 mg Chewable Tablets |
| United Kingdom | Montelukast 5 mg chewable tablets |

This leaflet was last revised in July 2019