

Package leaflet: Information for the user

MONTELUKAST Paediatric 5 mg Chewable tablets montelukast

Read all of this leaflet carefully before you start taking using 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you 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 Paediatric is and what it is used for
2. What you need to know before you 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. What MONTELUKAST Paediatric 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 Paediatric improves asthma symptoms and helps control asthma.

Your doctor has prescribed MONTELUKAST Paediatric to treat asthma, preventing your asthma symptoms during the day and night.

- MONTELUKAST Paediatric is used for the treatment of 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.

Your doctor will determine how MONTELUKAST Paediatric should be used depending on the symptoms and severity of you 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 Paediatric

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

Do not take 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 doctor or pharmacist before taking Montelukast Aurobindo

- If you or 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 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 Paediatric 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.

Use in children

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.

Other medicines and MONTELUKAST Paediatric

Some medicines may affect how MONTELUKAST Paediatric works, or MONTELUKAST Paediatric may affect how other medicines work.

Please tell your doctor or pharmacist if you or your child is taking or has recently taken other medicines, including those obtained without a prescription.

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 and alcohol

MONTELUKAST Paediatric 5 mg chewable tablets 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 and fertility

Use in 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.

Use in 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.

Ask your doctor or pharmacist for advice before taking this medicine.

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 contain aspartame, a source of phenylalanine. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that each MONTELUKAST Paediatric 5 mg chewable tablet contains phenylalanine (equivalent to 0.842 mg phenylalanine per 5 mg chewable tablet).

3. How to take MONTELUKAST Paediatric

- You or your child should take only one tablet of MONTELUKAST Paediatric 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.
- Always take MONTELUKAST Paediatric as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- 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 5 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 you or your child is taking MONTELUKAST Paediatric, be sure that you or your child does not take any other products that contain the same active ingredient, montelukast.

If you or your child takes more MONTELUKAST Paediatric 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 Paediatric or give MONTELUKAST Paediatric to your child

Try to take 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 a double dose to make up for a forgotten dose.

If you or your child stops taking MONTELUKAST Paediatric

MONTELUKAST Paediatric 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 Paediatric 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 this product, 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 5 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 were:

- 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 at a greater frequency in patients treated with montelukast than placebo (a pill containing no medication).

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

Very common (affects at least 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

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, disturbance in attention, memory impairment (*Rare*); hallucinations, disorientation, suicidal thoughts and actions (*Very rare*)]
- dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*)
- diarrhoea, 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 reactions (erythema multiforme) that may occur without warning (*Very rare*)
- joint or muscle pain, muscle cramps (*Uncommon*)
- fever (*Common*); weakness/tiredness, feeling unwell, swelling (*Uncommon*).

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 you get one or more of these symptoms.

Ask your doctor or pharmacist for more information about side effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist. 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 after 'EXP' on the blister and carton. The expiry date refers to the last day of that month.

Store below 25°C.

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

[HDPE bottle of 500 tablets]

Use within 12 months after first opening the HDPE bottle.

Do not throw away any medicine 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 is equivalent to 5 mg montelukast.
- The other ingredients are mannitol (E421), cellulose, microcrystalline, hydroxypropyl cellulose 2% (6 to 10 mpaS), croscarmellose sodium, iron oxide red (E172), aspartame (E951), artificial cherry flavour (contains flavouring ingredients and modified food starch) and magnesium stearate.

What MONTELUKAST Paediatric looks like and contents of the pack

Chewable tablets

Pink colored, mottled, round, biconvex, uncoated tablets debossed with 'X' on one side and '53' on other side.

MONTELUKAST Paediatric chewable tablets are available in PVC/ Polyamide/ Aluminium foil/ PVC blister pack and HDPE bottle with polypropylene closure containing silica gel desiccant.

Presentations

Blister pack: 7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98, 100, 140 and 200 chewable tablets.

HDPE bottle pack: 30, 90 and 500 chewable tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

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

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| France | MONTELUKAST ARROW LAB 5 mg, comprimé à croquer |
| Germany | Montelukast Aurobindo 5 mg Kautabletten |

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|----------------|--|
| Ireland | MONTELUKAST Paediatric 5 mg Chewable Tablets |
| Italy | Montelukast Aurobindo Pharma Italia 5 mg Compressa masticabile |
| Malta | Montelukast Aurobindo 5 mg Chewable Tablets |
| Netherlands | Montelukast Aurobindo 5 mg, kauwtabletten |
| Poland | Montelukast Aurovitas |
| Portugal | Montelucaste Aurobindo 5 mg comprimidos para mastigar |
| Romania | Montelukast Aurobindo 5 mg Comprimate masticabile |
| Spain | Montelukast Aurobindo 5 mg comprimidos masticables EFG |
| United Kingdom | Montelukast 5 mg chewable tablets |

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