



RELIEFAST[®]

Montelukast 4 mg

Chewable tablets

Read this entire leaflet carefully before your child starts taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Reliefast 4 mg, chewable tablets is and what it is used for

Reliefast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, **Reliefast** improves asthma symptoms and helps control asthma.

Your doctor has prescribed **Reliefast** to treat your child's asthma, preventing asthma symptoms during the day and night.

- **Reliefast** is used for the treatment of 2 to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- **Reliefast** 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.
- **Reliefast** also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how **Reliefast** 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. Before you take Reliefast 4 mg, chewable tablets

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

Do not give Reliefast to your child if he/she

- is allergic (hypersensitive) to montelukast or any of the other ingredients of **Reliefast** (see 6. Further information).

Take special care with Reliefast

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral **Reliefast** 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.
- It is important that your child take all asthma medications prescribed by your doctor. **Reliefast** 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 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.

Taking other medicines

Some medicines may affect how **Reliefast** works, or **Reliefast** may affect how your child's other medicines work.

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

Tell your doctor if your child is taking the following medicines before starting **Reliefast**:

- phenobarbital (used for treatment of epilepsy),
- phenytoin (used for treatment of epilepsy),
- rifampicin (used to treat tuberculosis and some other infections).

Food and drink

Reliefast 4 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

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

This subsection is not applicable for **Reliefast** 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: Women who are pregnant or intend to become pregnant should consult their doctor before taking **Reliefast**. Your doctor will assess whether you can take **Reliefast** during this time.

Use in breast-feeding: It is not known if **Reliefast** appears in breast milk. You should consult your doctor before taking **Reliefast** if you are breast-feeding or intend to breast-feed.

Driving and using machines

This subsection is not applicable for the **Reliefast** 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.

Reliefast 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.

Important information about some of the ingredients of Reliefast 4 mg chewable tablets

Reliefast 4 mg chewable tablets 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 4 mg chewable tablet contains phenylalanine (equivalent to 0.674 mg phenylalanine per 4 mg chewable tablet).

3. How to take Reliefast 4 mg, chewable tablets

- This medicine is to be given to a child under adult supervision.
- Your child should take only one tablet of **Reliefast** once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.
- Always have your child take **Reliefast** as your doctor has told you. You should check with your child's doctor or pharmacist if you are not sure.
- To be taken by mouth.

For children 2 to 5 years of age:

One 4 mg chewable tablet daily, to be taken in the evening. **Reliefast** 4 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 your child is taking **Reliefast**, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

For children 2 to 5 years old, **Reliefast** 4 mg chewable tablets are available.

For children 6 to 14 years old, **Reliefast** 5 mg chewable tablets are available.

Reliefast 4 mg chewable tablets, is not recommended below 2 years of age.

If your child takes more Reliefast 4 mg, chewable tablets 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, vomiting, and hyperactivity.

If you forget to give Reliefast 4 mg, chewable tablets to your child

Try to give **Reliefast** as prescribed. However, if 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 Reliefast 4 mg, chewable tablets

Reliefast can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking **Reliefast** 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 product, ask your child's doctor or pharmacist.

4. Possible side effects

Like all medicines, **Reliefast** 4 mg, chewable tablets can cause side effects, although not everybody gets them.

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

- abdominal pain
- thirst

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

- Headache

This side effect was usually mild and occurred at a greater frequency in patients treated with montelukast tablets than placebo (a pill containing no medication).

Additionally, the following side effects have been reported:

- increased bleeding tendency,
- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing,
- behaviour and mood related changes: dream abnormalities, including nightmares, hallucinations, irritability, feeling anxious, restlessness, agitation including aggressive behaviour, tremor, depression, trouble sleeping suicidal thoughts and actions (in very rare cases),
- dizziness, drowsiness, pins and needles/numbness, seizure,
- palpitations,
- nosebleed,
- diarrhoea, dry mouth, indigestion nausea, vomiting,
- hepatitis,
- bruising, itching, hives, tender red lumps under the skin most commonly on your shins (erythema nodosum),
- joint or muscle pain, muscle cramps,
- Tiredness, feeling unwell, swelling, fever.

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 your child gets one or more of these symptoms.

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

5. How to store Reliefast 4 mg, chewable tablets

- Keep out of the reach and sight of children.
- Do not use **Reliefast** after the expiry date which is stated on the blister or outer package.
- Store below 25°C. Store in the original package, in order to protect from light and moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Reliefast 4 mg, chewable tablets contains

Active substance: montelukast (as montelukast sodium).

One chewable tablet contains montelukast sodium, which is equivalent to 4 mg montelukast.

Excipients: Microcrystalline cellulose, mannitol, croscarmellose sodium, iron oxide red (E172), hydroxypropylcellulose, cherry flavour, aspartame (E951), magnesium stearate.

What Reliefast 4 mg, chewable tablets looks like and contents of the pack

Reliefast 4 mg chewable tablets are pink, biconvex, round tablets, debossed "4" on one side.

Reliefast 4 mg, chewable tablets is available in packs of 28 tablets.

Manufactured by: Pabianickie Zakłady Farmaceutyczne Polfa S.A.
Pabianice, Poland

For: ARWAN Pharmaceutical Industries Lebanon s.a.l.
Jadra, Lebanon

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists