

REOVAIR® Paediatric 5 mg

Chewable Tablets

Montelukast

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 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.

In this leaflet:

1. What REOVAIR Paediatric is and what it is used for
2. What you need to know before you take REOVAIR Paediatric
3. How to take REOVAIR Paediatric
4. Possible side effects
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1. What REOVAIR Paediatric is and what it is used for

What REOVAIR Paediatric is

Reovair Paediatric contains the active substance Montelukast which belongs to a group of medicine called leukotriene receptor antagonist that blocks substance called leukotrienes.

How REOVAIR Paediatric works

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, REOVAIR Paediatric improves asthma symptoms and helps control asthma.

When REOVAIR Paediatric should be used

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

- REOVAIR Paediatric is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.
- REOVAIR 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.
- REOVAIR Paediatric also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how REOVAIR 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 REOVAIR Paediatric

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

Do not take REOVAIR 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 you or your child take REOVAIR Paediatric.

- If you or your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral REOVAIR 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.
- 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.

Children and adolescents

Do not give this medicine to children less than 6 years of age.

Other medicines and REOVAIR Paediatric

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 REOVAIR Paediatric works, or REOVAIR Paediatric may affect how other medicines work.

Tell your doctor if you or your child is taking the following medicines before starting REOVAIR Paediatric:

- Phenobarbital (used for treatment of epilepsy)
- Phenytoin (used for treatment of epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections)

REOVAIR Paediatric with food and drink

REOVAIR Paediatric 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or two 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 REOVAIR Paediatric.

Pregnancy

Your doctor will assess whether you can take REOVAIR Paediatric during this time.

Breast-feeding

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

Driving and using machines

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

3. How to take REOVAIR Paediatric

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 REOVAIR 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.

For children 6 to 14 years of age:

- The recommended dose is one 5 mg chewable tablet daily to be taken in the evening.
- If you or your child is taking REOVAIR Paediatric, be sure (that you or your child) does 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.
- REOVAIR Paediatric 5 mg chewable tablets should not be taken immediately with food; it should be taken at least 1 hour before or two hours after food.

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

Try to take REOVAIR Paediatric 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 stop taking REOVAIR Paediatric

REOVAIR 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 REOVAIR 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 Paediatric 5 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Montelukast Paediatric 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).

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 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

- Behavior and mood related changes: agitation including aggressive behavior 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

- Behavior 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 tract infection

Common: the following may affect up to 1 in 10 people

- Diarrhea, nausea, vomiting
- Rash
- Fever
- Elevated liver enzymes

Uncommon: the following may affect up to 1 in 100 people

- Behavior and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, and 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

- Behavior and mood related changes: disturbance in attention, memory impairment, and 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)

Reporting side effects:

If any of the side effects gets serious, or if you notice any possible side effects not listed in this leaflet, please tell your doctor or pharmacist. You can also report side effect directly (see section 6). By reporting side effect you can help provide more information on the safety of this medicine.

5. How to store REOVAIR Paediatric

- Keep this medicine out of the sight and reach of children.
- Do not use REOVAIR Paediatric 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. Further information

What REOVAIR Paediatric 5 mg contains

The active substance is montelukast, REOVAIR Paediatric 5 mg chewable tablet contains montelukast sodium which corresponds to 5 mg of montelukast.

- The other ingredients are: mannitol, microcrystalline cellulose, hydroxy propyl cellulose, red iron oxide, croscarmellose sodium, bubble gum flavor, colloidal silicon dioxide, and magnesium stearate.

What REOVAIR Paediatric 5 mg looks like and contents of the pack

REOVAIR Paediatric 5 mg chewable tablets are pink, compact, biconvex, round tablet, embossed "A9" on one side.

REOVAIR Paediatric 5 mg is available in blister packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

Alrai Pharmaceutical Industries Co. (L.L.C.)

Al Wadi - 2, Almu'tasem Bellah Al Fatemy Street

P.O.Box: 9224 Jeddah - 21413 Kingdom of Saudi Arabia

Tel: +966 12 2889949

Fax: +966 12 2889014

E-mail: info@alraipharma.com

This leaflet was last approved in 09/2019, Revision 0.

To report any side effect(s):

Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662

Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.

Toll free phone: 8002490000

E-mail: npc.drug@sfd.gov.sa

Website: www.sfd.gov.sa/npc

Other GCC States:

Please contact the relevant competent authority

THIS IS A MEDICATION

- Medication 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 medication.
- The doctor and the pharmacist are the 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 medications out of reach of children.

Council of Arab Health Ministers
Union of Pharmacists



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ALRAI Pharmaceutical Industries Co. (L.L.C.)
Jeddah-Kingdom of Saudi Arabia

