

Patient Information Leaflet

ALUKON® 4 mg granules

Montelukast

Read all of this leaflet carefully before you start giving this medicine to your child because it contains important information for you. If you have questions or you notice side effects not mentioned in this leaflet, contact your doctor or pharmacist. This medicine has been prescribed for your child only. Do not pass this medicine on to others. It may harm them, even if their signs of illness are the same as your child's.

1. What Alukon is and what it is used for

Alukon (montelukast) is a leukotriene receptor antagonist that blocks leukotrienes (ATC code: R03D C03). Leukotrienes cause narrowing and swelling of the respiratory airways in the lungs and also induce allergy symptoms. By blocking leukotrienes, Alukon improves asthma symptoms and helps control asthma.

When to use Alukon? The doctor has prescribed Alukon 4 mg granules to your child to treat your child's asthma and to prevent his/her asthmatic symptoms during daytime and at night. Alukon 4 mg is used for treating children 6 months to 5 years of age who are inadequately controlled with their current therapy and who require additional treatment. Alukon 4 mg may also be an alternative to inhaled corticoids in patients 2 to 5 years of age who have not recently taken oral corticoids for their asthma and who demonstrate inability to use corticoids when administered via inhalation. Alukon 4 mg also helps prevent respiratory airway narrowing triggered by effort in children 2 years of age and over. The doctor will determine how you should use Alukon 4 mg, depending on your child's symptoms and the severity of his/her asthma.

What is asthma? Asthma is a long-term disease which includes: difficulty breathing due to narrowing of the respiratory airways, worsening and improving as a result of various conditions; sensitivity of the respiratory airways, reacting to many factors such as cigarette smoke, pollens, cold air, or effort; swelling (inflammation) of the respiratory airway lining. Asthma symptoms include: coughing, wheezing and chest tightness.

2. What you need to know before you give Alukon 4 mg granules to your child

Tell the doctor if your child has, or has had, any medical problems or allergies.

Do not give Alukon

if your child is allergic (hypersensitive) to Montelukast or to any other ingredient of this medicine listed in section 6.

Warnings and precautions

Consult the doctor or pharmacist before giving Alukon 4 mg granules to your child.

If your child's asthma or breathing becomes worse, tell the doctor immediately.

Alukon is not intended for the treatment of acute asthma attacks: if an attack occurs, follow the instructions given to you by your doctor for your child and always have your child's inhaled rescue medicine for asthma attacks with you.

It is important that your child takes all the anti-asthmatic medicines prescribed to him/her by the doctor. Alukon should not be substituted for any other anti-asthmatic medicines prescribed to your child by the doctor.

Any patient treated with anti-asthmatic medication should know that if they develop a combination of symptoms, such as influenza-like illness, tingling or numbness in the arms or legs, worsening of their lung symptoms, and/or skin rash, they must consult their doctor.

Your child must not take any acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as nonsteroidal anti-inflammatory drugs or NSAIDs) if they make his/her asthma worse.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported with montelukast in adults, adolescents and children. If your child develops such symptoms while taking Alukon, you should consult your child's doctor.

Children

Do not give this medicine to children under 6 months of age.

Other medicines and Alukon

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

Some medicines can affect the way Alukon works, or Alukon may affect the way other medicines work.

Before you start giving Alukon 4 mg granules to your child, tell your doctor if your child is taking any of the following medicines: phenobarbital (for treatment of epilepsy); phenytoin (for treatment of epilepsy); rifampicin (medicine for tuberculosis and certain other infections).

Alukon with food and drink

Alukon 4 mg granules can be taken during or outside meals.

Pregnancy and breast-feeding

Since Alukon 4 mg granules is intended for use in children 6 months to 5 years of age, this subsection is not applicable.

Driving and using machines

Because Alukon 4 mg granules is intended for children, this section contains the information regarding the active ingredient montelukast. It is unlikely that montelukast may have effects on the ability to drive or use machines. However, response to the medicine may vary from one person to another. Some side effects (such as dizziness and drowsiness) which may affect your ability to drive or use machines have very rarely been reported with montelukast.

3. How to give Alukon 4 mg granules to your child?

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.

The usual dose for children 6 months to 5 years of age is one (1) sachet of Alukon 4 mg granules to be taken by mouth each evening.

Alukon 4 mg granules should not be taken with other medicines containing the same active ingredient, montelukast.

This medicine must only be administered to a child under adult supervision. Your child must take it even if no symptoms are present, or in case of an acute asthma attack.

Alukon 4 mg granules is not recommended in children less than 6 months of age

How to administer Alukon 4 mg granules to my child?

- Only open the sachet at the time of giving the medicine.
- You may administer Alukon 4 mg granules directly into the mouth, OR mix the full contents of the Alukon 4 mg sachet with one spoonful of soft food, either cold or at room temperature (for example, apple sauce, ice-cream, carrots and rice), making sure that the full dose is mixed with the food.
- Ensure that the child receives immediately (within 15 minutes) the full spoonful of mixed granules/food. IMPORTANT: Do not store any mixed granules/food for later use.
- Alukon 4 mg granules are not intended to be dissolved in a drink; however, your child may drink after having swallowed the granules.
- Alukon can be taken during or outside meals.

If your child has taken more Alukon 4 mg granules than he/she should

Immediately contact your child's doctor or the pharmacist. The most commonly reported symptoms in overdose cases in adults and children are: abdominal pain, thirst, drowsiness, headache, diarrhoea, nausea, vomiting, increased liver enzymes, and hyperactivity.

If you forget to give your child Alukon 4 mg granules

Always try to give Alukon as prescribed by the doctor. However, if you forget to give your child a dose, simply continue the treatment as usual, giving one sachet per day. Do not use a double dose to make up for a forgotten dose.

If your child stops taking Alukon 4 mg granules

Alukon can only treat your child's asthma if he/she continues taking it. It is important that your child continues taking Alukon 4 mg granules for as long as the doctor has prescribed it. This 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 your pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Immediately consult your child's doctor if your child develops one or more of following serious side effects (your child may require emergency medical treatment):

Uncommon Allergic reactions, including skin rash, swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing; behavioural and mood changes, agitation including aggressive behaviour or hostility, depression; seizure ; **Rare** increased bleeding tendency, tremor, palpitations **Very rare** flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and or rash (Churg-Strauss syndrome), low blood platelet count, hallucinations, disorientation; swelling of the lungs, severe skin reactions (erythema multiforme) that may occur without warning; inflammation of the liver.

In clinical trials involving montelukast 4mg granules, the most frequently reported side effects (may affect up to 1 in 10) **are** diarrhoea, hyperactivity, asthma, scale and itchy skin, rash.

In addition, the following side effects have been reported in clinical studies involving montelukast: abdominal pain, headache, thirst. These effects were usually mild and occurred more frequently in patients treated with montelukast compared to patients receiving a tablet containing no medicine.

The following side effects were reported **while medicines containing montelukast have been on the market**: *Very common*: Upper respiratory tract infections. *Common*: diarrhoea, nausea, vomiting, fever, elevated liver enzymes. *Uncommon*: Behavioural and mood changes [abnormal dreams including nightmares, sleep disorders, sleepwalking, irritability, anxiety, restlessness]; dizziness, drowsiness, stinging and tingling/numbness; nose bleeds; dry mouth, indigestion; bruising, itching, hives; joint or muscle pain, muscle cramps, bedwetting in children; fatigue, malaise, swelling. *Rare*: disturbance in attention, memory impairment, uncontrolled muscle movements; *Very rare*: painful red nodules under the skin, most often in the shins (erythema nodosum); obsessive-compulsive symptoms; stuttering.

If you notice any side effect in your child, talk to your child's doctor or to the pharmacist. This also includes any side effects not listed in this leaflet.

5. How to store Alukon 4 mg granules?

Keep out of the reach and sight of children.

Store below 30°C, in the original package to protected from light and humidity.

Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment. Ask your doctor or pharmacist for help disposing of unused medicine.

6. Contents of the pack and other information

What Alukon 4 mg granules contains

The active substance is montelukast. One sachet of granules contains 4 mg of montelukast (in the form of montelukast sodium)

The other ingredients are mannitol, hydroxypropylcellulose, magnesium stearate.

What Alukon 4 mg granules looks like and content of the pack

Sachet with white, homogeneous granules, one dose per sachet.

Cardboard box with 14 sachets.

Alukon 4 mg granules is a prescription only medicine.

Manufacturer

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