

**Patient Information Leaflet**  
**ALUKON® 5 mg chewable tablet**

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 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 5 mg chewable tablet to your child to treat your child's asthma and to prevent his/her asthmatic symptoms during daytime and at night. Alukon 5 mg is used for treating children 6 to 14 years of age who are inadequately controlled with their current therapy and who require additional treatment. Alukon 5 mg may also be an alternative to inhaled corticoids in patients 6 to 14 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 5 mg also helps prevent respiratory airway narrowing triggered by effort. The doctor will determine how you should use Alukon 5 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 5 mg chewable tablet 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 5 mg chewable tablet 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 years of age. Alukon 4 mg granules are available to treat children 6 months to 5 years.

**Other medicines and Alukon**

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 5 mg chewable tablet 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 5 mg chewable tablet should not be taken with food; it be taken at least 1 hour before or 2 hours after food.

**Pregnancy and breast-feeding**

Although the topic is not application for children the information for the active ingredient montelukast is inserted. Pregnant women or women who plan a pregnancy and women who are breast-feeding or intend to breastfeed should seek medical advice before taking this medication.

**Driving and using machines**

Because Alukon 5 mg chewable tablet 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.

**Important information about some ingredient of Alukon 5 mg chewable tablet**

Each chewable tablet contains 1.7 mg aspartame (E951). Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

**3. How to give Alukon 5 mg chewable tablet 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 to 14 years of age is one (1) Alukon 5 mg chewable tablet to be taken by mouth each evening. The tablet should be chewed before swallowing; 1 hour before or 2 hours after intake of food.

Alukon 5 mg chewable tablet 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.

**If your child has taken more Alukon 5 mg chewable tablet 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 5 mg chewable tablet**

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 tablet per day. Do not use a double dose to make up for a forgotten dose.

**If your child stops taking Alukon 5 mg chewable tablet**

Alukon can only treat your child's asthma if he/she continues taking it. It is important that your child continues taking Alukon 5 mg chewable tablet 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 the 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 5mg chewable tablet, the most frequently reported side effect** (may affect up to 1 in 10) **is** headache. In addition, the following side effect has been reported in clinical studies involving montelukast 10 mg filmcoated tablets: abdominal pain. 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, rash, 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 5 mg chewable tablet?**

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 5 mg chewable tablet contains**

The active substance is montelukast. Each chewable tablet contains 5 mg of montelukast (in the form of montelukast sodium)

The other ingredients are Red iron oxide (E172), microcrystalline cellulose, mannitol, croscarmellose sodium, Low-substituted hydroxypropylcellulose, aspartame, black cherry essence, magnesium stearate.

### **What Alukon 5 mg chewable tablet looks like and content of the pack**

Blister with 14 pink, round biconvex chewable tablets.

Box with 28 tablets (2 blisters).

**Alukon 5 mg chewable tablet** is a prescription only medicine.

### **Manufacturer**

Bilim İlaç San. Ve Tic A.Ş. Gebze Organize Sanayi Bölgesi 1900 Sokak No: 1904 41480 Gebze, Kocaeli, Turkey.

**Marketing Authorisation Holder**

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