

## Patient Information Leaflet

### ALUKON® 10 mg film-coated tablet

#### Montelukast

**Read all of this leaflet carefully before you start taking this medicine 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 you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

#### 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, helps control asthma, and ameliorates seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

**When to use Alukon ?** Your doctor has prescribed Alukon to you to treat your asthma preventing your asthma symptoms during the day and at night. Alukon 10 mg film-coated tablet is used for treating adults and adolescents aged 15 years or older who are inadequately controlled with their current medication and who require additional treatment. Alukon 10 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 also helps prevent respiratory airway narrowing triggered by effort. In asthmatic patients for whom Alukon is indicated, Alukon may also provide relief from seasonal allergic rhinitis symptoms. Your doctor will determine how you should use Alukon, depending on your symptoms and the severity of your asthma.

**What is asthma?** Asthma is a long-lasting 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.

**What are seasonal allergies (also known as hay fever or seasonal allergic rhinitis)?** Seasonal allergies are allergic reactions that are often due to the airborne pollens of trees, grasses and herbaceous plants. Symptoms typically include: stuffy, runny and itchy nose; sneezing; watery, swollen, red and itchy eyes.

## **2. What you need to know before you take Alukon 10 mg film-coated tablet**

Tell your doctor if you have, or have had any medical problems or allergies.

### **Do not take Alukon**

If you are allergic (hypersensitive) to Montelukast or to any other ingredient of this medicine listed in section 6.

### **Warnings and precautions**

Please consult your doctor or pharmacist before taking Alukon.

If your asthma or breathing becomes worse, tell your 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 and always have your inhaled rescue medicine for asthma attacks with you.

It is important that you or your child take all the anti-asthmatic medicines prescribed by your doctor. Alukon must not replace any other anti-asthmatic medicine prescribed to you by your 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.

Do not take any acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as nonsteroidal anti-inflammatory drugs or NSAIDs) if they make your 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 you develop such symptoms while taking Alukon, you should consult your doctor.

### **Children and adolescents**

Do not give this medicine to children aged under 15 years.

Different forms of this medicine are available for children under 15 years, depending on their age.

### **Other medicines and Alukon**

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 using Alukon 10 mg film-coated tablet, tell your doctor if you take any of the following medicines:

- phenobarbital (for treatment of epilepsy);
- phenytoin (for treatment of epilepsy);
- rifampicin (medicine for tuberculosis and certain other infections).
- gemfibrozil (medicine for high plasma lipid levels).

### **Alukon with food and drink**

Alukon 10 mg film-coated tablet can be taken during or outside meals.

### **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 this medicine.

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

*Breast-feeding:* It is not known whether montelukast passes into breast milk.

### **Driving and using machines**

It is unlikely that montelukast may have effects on your 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 10mg film-coated tablet**

**It contains lactose:** if your doctor has told you that you have an intolerance to certain types of sugar, please contact him/her before you take this medicine.

## **3. How to take Alukon 10 mg film-coated tablet?**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In adults and adolescents aged 15 years or older, the usual dose is 1 tablet of 10mg taken daily in the evening, by mouth.

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

### **If you take more Alukon than you should**

Immediately contact your doctor or pharmacist. If you have swallowed too many tablets, or if you believe a child may have swallowed one of the tablets, immediately call the nearest emergency room or your doctor. Overdose symptoms are stomach pain, drowsiness, thirst, headache, vomiting and hyperactivity (involuntary movements). Take this leaflet and any remaining tablets with you to show them to the doctor.

**If you forget to take your tablet**

Simply take your next tablet at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Alukon**

It is important to continue taking Alukon for as long as your doctor has prescribed it, whether or not symptoms are present. This will help control your asthma. Alukon can only treat your asthma if it is taken continuously.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

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

**Immediately tell your doctor if you develop any of the following serious side effects** (you 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, suicidal thoughts and actions; swelling of the lungs; severe skin reactions, inflammation of the liver.

**In clinical trials involving montelukast 10mg film-coated tablet, the most frequently reported side effects** (may affect up to 1 in 10) are abdominal pain and headache.

These effects were usually mild and occurred more frequently in patients treated with montelukast compared to patients receiving a tablet containing no medicine.

In addition, 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, abnormal liver function test results. *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*: attention disorder, 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 experience any side effect, talk to your doctor or pharmacist. This also includes any side effects not listed in this leaflet.

## **5. How to store Alukon 10 mg film-coated tablets?**

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 10 mg film-coated tablet contains**

The active ingredient is montelukast. One film-coated tablet contains 10 mg of montelukast (in the form of montelukast sodium)

The other ingredients are anhydrous lactose, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate. The tablet film-coating contains hydroxypropyl cellulose (E463), hypromellose (E464), titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172).

### **What Alukon 10 mg film-coated tablet looks like and content of the pack**

Light yellow, round, biconvex film-coated tablet.

Box with 28 tablets.

**Alukon 10 mg film-coated 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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**Date of revision of the leaflet**

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