

PATIENT INFORMATION LEAFLET

BRONCHOREST® 4 mg/2.5 mg chewable tablet

It is taken orally.

- **Active ingredient(s):** It contains 4.157 mg montelukast sodium equivalent to 2.5 mg levocetirizine dihydrochloride and 4 mg montelukast.
- **Excipient(s):** Microcrystalline cellulose pH 112, maltitol (E965), low substituted hydroxypropyl cellulose, croscarmellose sodium, red iron oxide, sucralose, gum flavor, magnesium stearate, lactose monohydrate, colloidal anhydrous silica, tutti frutti flavor.

Read this INSTRUCTIONS FOR USE carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again later.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *While using this medicine, tell your doctor or hospital that you are using this medicine.*
- *Follow these instructions exactly. Do not use higher or lower doses of the medication than those recommended.*

In this User Manual:

1. *What is BRONCHOREST® and what is it used for?*
2. *Things to consider before using BRONCHOREST®*
3. *How to use BRONCHOREST®?*
4. *What are the possible side effects?*
5. *Storing BRONCHOREST®*

Headings are included.

1. What is BRONCHOREST® and what is it used for?

BRONCHOREST® They are flat, round chewable tablets with one side pink or pinkish and the other side white or whitish, containing 2.5 mg levocetirizine dihydrochloride and 4 mg montelukast.

Levocetirizine is an antihistamine used to treat allergies. Antihistamines counteract the effects of histamine, relieving allergy symptoms. Montelukast is a leukotriene receptor antagonist (an antagonist) that blocks substances called leukotrienes. By blocking leukotrienes, it improves asthma symptoms. Montelukast is not a steroid (a fatty organic compound related to cholesterol).

BRONCHOREST® It is indicated for the treatment and relief of symptoms of allergic rhinitis (cold) and asthma accompanied by allergic rhinitis.

What is asthma?

Asthma is a persistent (chronic) inflammation of the bronchial airways, the tubes that carry air from outside the body to the lungs. Symptoms of asthma include:

- Cough
- Wheezing
- Chest tightness
- Shortness of breath

What is allergic rhinitis?

- Seasonal allergic rhinitis, also known as hay fever, is triggered by allergens found outside the home, such as tree, grass, and weed pollens.
- Perennial allergic rhinitis can occur year-round and is usually triggered by indoor allergens such as house dust mites, animal dander, and/or mold spores.
- Symptoms of allergic rhinitis may include:
 - Nasal congestion, runny and/or itchy nose
 - Sneeze

2. Things to consider before using BRONCHOREST®**DO NOT USE BRONCHOREST® in the following situations:**

If:

- If you are hypersensitive to any of the ingredients in this product (allergic reactions may occur as skin rash, itching, swelling of the face, lips, hands/feet or difficulty breathing)
- If you have severe renal failure (if the rate of clearance of creatinine, a substance used to monitor kidney function, from the blood is below 10 ml/min)

USE BRONCHOREST® WITH CAUTION in the following situations:

- Use caution when taking BRONCHOREST® with alcohol. Although racemic cetirizine has been shown not to potentiate the effects of alcohol, in susceptible patients, concomitant use of cetirizine or levocetirizine with alcohol or other drugs that affect the brain may have an adverse effect on alertness.
- If you are unable to empty your bladder (such as due to spinal cord injury or enlarged prostate), consult your doctor.
- If your asthma or breathing gets worse, tell your doctor immediately.
- BRONCHOREST® has not been proven effective in treating acute asthma attacks. If you experience an attack, follow your doctor's instructions. Always carry your inhaled rescue medicine for asthma attacks with you.
- It is important to take all your asthma medications as prescribed by your doctor. BRONCHOREST® should not be used in place of other asthma medications prescribed by your doctor.
- All patients taking anti-asthma medications should be advised to contact their physician if they experience any combination of flu-like symptoms, numbness or tingling in the arms or legs, worsening lung symptoms, and/or rash.

- If you have asthma and your asthma gets worse when you take acetylsalicylic acid (aspirin), try not to take aspirin or other painkillers called non-steroidal anti-inflammatory drugs while you are taking BRONCHOREST®.

Various neuropsychiatric events (e.g., changes in behavior and mood, depression, and suicidality) have been reported in patients of all ages treated with Montelukast (see section 4). If you develop such symptoms while taking Montelukast, you should contact your doctor.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using BRONCHOREST® with food and drink

BRONCHOREST® can be taken with meals or between meals.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

If you are pregnant or planning to become pregnant, inform your doctor. Your doctor will decide whether or not you should use BRONCHOREST®.

If you realise that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using the medicine.

BRONCHOREST® should not be used during breastfeeding.

Use of vehicles and machinery

BRONCHOREST® Some patients taking levocetirizine, one of the active ingredients in , have experienced drowsiness, fatigue, and tiredness. If you are considering potentially hazardous activities, driving, or operating machinery, it is recommended that you wait until you see your response to treatment and proceed with caution. However, specialized testing has shown no impairment of mental confusion, reaction time, or driving ability after taking recommended doses of levocetirizine.

BRONCHOREST® Certain side effects (dizziness and drowsiness) reported very rarely with montelukast, one of the active ingredients of may affect some patients' ability to drive or operate machinery.

Important information about some of the ingredients contained in BRONCHOREST®

This medicinal product contains maltitol (E 965) and lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, i.e. it is essentially “sodium-free”.

Use with other drugs

Interactions associated with levocetirizine

In sensitive patients, concomitant use of cetirizine or levocetirizine with other drugs that affect the central nervous system may have an adverse effect on alertness.

Interactions associated with Montelukast

Some medicines may change the way BRONCHOREST® works, or BRONCHOREST® may change the way your other medicines work. If you are taking the following medicines, tell your doctor before starting BRONCHOREST®:

- Phenobarbital (used to treat epilepsy)
- Phenytoin (used to treat epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections)
- Gemfibrozil (used to treat high levels of fat in the liquid part of the blood outside the cells)

If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about them.

3. How to use BRONCHOREST®?**• Instructions for proper use and dosage/frequency of administration:**

Children aged 15 years and over and adults: Take two BRONCHOREST® 4/2.5 mg chewable tablets once a day.

Children aged 2-14 years: One BRONCHOREST® 4/2.5 mg chewable tablet is used once a day.

For compliance, patients taking levocetirizine and montelukast as separate tablets may switch to BRONCHOREST®, which contains the same component doses.

The therapeutic effect of BRONCHOREST® on allergic rhinitis and allergic asthma begins within one day. Patients should be advised to continue taking BRONCHOREST® during periods of allergic contact.

• Application route and method:

- BRONCHOREST® is taken orally by chewing.
- There is no harm in taking BRONCHOREST® on an empty or full stomach.

• Different age groups:**Use in children:**

BRONCHOREST® It is not recommended for use in children and infants under 2 years of age due to lack of data.

Use in the elderly:

No dosage adjustment is necessary in elderly patients with normal renal function.

- **Special use cases:**

Kidney/Liver failure:

Patients with kidney failure may be given a lower dose depending on the severity of their disease. In children, the dose is determined by body weight. Your doctor will determine the dose.

Do not use if you have severe kidney failure.

If you have only liver failure, you can use the generally recommended dose. However, there is no data available on patients with severe liver failure.

Patients with both hepatic and renal failure may be given a lower dose depending on the severity of their renal disease.

If BRONCHOREST® If you have the impression that the effect of is too strong or too weak, talk to your doctor or pharmacist.

If you use more BRONCHOREST® than you should:

Adults may experience drowsiness. Children may experience restlessness and drowsiness followed by restlessness.

BRONCHOREST® No side effects have been reported in cases of overdose for montelukast, one of the active ingredients. The most common side effects in adults and children with overdose are abdominal pain, drowsiness, thirst, headache, vomiting, and hyperactivity.

BRONCHOREST® If you have used more than you should, talk to a doctor or pharmacist.

If you forget to use BRONCHOREST®

Try to take your medication as recommended.

If you forget to take a dose, skip that dose and continue with normal use.

Do not take a double dose to make up for a forgotten dose.

Possible effects when treatment with BRONCHOREST® is stopped

If you encounter any problems with the use of BRONCHOREST®, consult your doctor or pharmacist.

BRONCHOREST® If used for a shorter duration than prescribed, no harmful effects are expected. However, it should be noted that in this case, symptoms may reoccur, although less severe than before starting BRONCHOREST® treatment.

4. What are the possible side effects?

Like all medicines, BRONCHOREST® may cause side effects in people who are sensitive to the ingredients it contains.

If any of the following occur, stop using BRONCHOREST® and immediately contact your doctor or go to the emergency department of the nearest hospital:

- Allergic reaction (hypersensitivity reaction) including swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden drop in blood pressure that can be fatal, leading to fainting or shock
- A seizure condition characterized by involuntary, violent contractions (convulsions)
- Flu-like illness, numbness, tingling and loss of sensation in the arms and legs, worsening respiratory symptoms and/or rash

- Inflammation of the liver (hepatitis)
- Palpitation
- Shortness of breath
- visual impairment
- Increased heart rate above normal (tachycardia)

These are all very serious side effects. If you experience any of them, you may have a severe allergy to BRONCHOREST®. You may need immediate medical attention or hospitalization.

Side effects are described as shown in the following categories:

Very common :Can be seen in at least 1 in 10 patients.

Widespread : It can be seen in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon : It may be seen in less than 1 in 100 patients, but more than 1 in 1,000 patients.

Sparse It may be seen in less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare : It may be seen in less than one in 10,000 patients.

Unknown frequency : It may be seen in too few patients to be determined with the available data.

Very common:

- Upper respiratory tract infection

Widespread:

- Headache
- tendency to sleep
- Dry mouth
- Thirst
- Somnolence
- Weakness
- Diarrhea
- Nausea
- Vomiting
- Debris
- Fire
- Stomach ache
- Increased liver enzymes

Uncommon:

- Fatigue
- Indigestion
- Sleep disorders
- Dream abnormalities, including nightmares
- Insomnia
- Irritability

- Anxiety
- Unrest
- Aggressive behavior or hostility
- Sleepwalking
- Depression
- dizziness
- tingling sensation
- Loss of sensation
- Having a seizure
- nosebleeds
- Bruise
- Itching
- Hives
- Joint pain
- Muscle pain, including muscle cramps
- Blisters on the legs
- Stomach ache
- General weakness (asthenia)

Sparse:

- Increased tendency to bleed
- Shake
- Palpitation
- Attention deficit
- Forgetfulness

Very rare:

- Hallucination (seeing things that do not actually exist)
- Disorientation (loss of awareness of time and space)
- Suicidal ideation and behavior (including suicide)
- Behavioral changes
- Hepatitis (liver inflammation)
- Red, painful swelling under the skin, most commonly in the area above your shinbone (erythema nodosum), or severe skin reactions that appear suddenly without any other symptoms (erythema multiforme)
- Swelling (inflammation) of the lungs

Unknown:

- Increased appetite
- Irritability
- Contractions
- Dizziness
- Fainting

- Taste disturbance
- visual impairment
- Blurred vision
- Difficulty breathing
- Burning during urination
- Inability to urinate completely
- Weight gain
- Abnormal liver function (abnormal liver test results)
- Vertigo (dizziness caused by imbalance)
- Oculogyration (Involuntary movement of the eyeball in any direction)

Very rare cases of a combination of flu-like illness, numbness or tingling in the arms or legs, worsening of lung symptoms, and/or rash (Churg-Stauss Syndrome) have been reported in patients treated with Montelukast. If you experience one or more of these symptoms, you should tell your doctor.

If you experience any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience any side effects, whether or not listed in the Instructions for Use, talk to your doctor, pharmacist or nurse. Also, report any side effects you experience. www.titck.gov.tr Report any side effects to the Turkish Pharmacovigilance Center (TÜFAM) by clicking the "Drug Side Effect Reporting" icon on the website or by calling the side effect reporting line at 0 800 314 00 08. By reporting any side effects you experience, you will contribute to the acquisition of more information about the safety of the medication you are using.

5. Storing BRONCHOREST®

BRONCHOREST® Keep out of sight and reach of children and in its packaging.

Store at room temperature below 25 °C. Protect from moisture and light.

Use in accordance with the expiration date.

Do not use BRONCHOREST® after the expiry date on the packaging.

Do not use BRONCHOREST® if you notice any damage to the product and/or its packaging.

Do not throw away expired or unused medications! Give them to the collection system designated by the Ministry of Environment, Urbanization and Climate Change.

You can access detailed and up-to-date information about this medicine by scanning the QR code with your smartphone/tablet or a QR code reader.

Marketing Authorization Holder:

SANTA FARMA ILAC SAN. A.S.

H. Edip Adivar / Boru Cicegi Sokak No: 16 Şişli, İstanbul, Türkiye

Manufacturer:

Santa Farma İlaç San. A.Ş.

Kocaeli, Gebze, V (Kimya) İhtisas OSB Erol Kiresepi Cad. No: 8, Dilovası, Kocaeli, Türkiye