

PATIENT INFORMATION LEAFLET

BRONCHOREST® 10 mg/5 mg capsule

Oral use.

- ✓ **Active ingredient:** Each capsule contains 10 mg of montelukast (equivalent to 10.40 mg of montelukast sodium) and 5 mg of levocetirizine dihydrochloride.
- ✓ **Excipients:** Microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, magnesium stearate, lactose DCL14(bovine), crospovidone, talc, sodium stearyl fumarate, HPMC 15 cP-Methocel, titanium dioxide, PEG 6000 and the capsule ingredients are patent blue v, quinoline yellow, titanium dioxide, water and gelatin(bovine).

Read all of this Patient Information Leaflet carefully before you start taking this medicine, because it contains important information for you.

- ✓ *Keep this leaflet because you may need to read it again.*
- ✓ *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- ✓ *This medicine has been prescribed for you. Do not pass it on to others.*
- ✓ *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital*
- ✓ *Strictly follow these Patient Information Leaflet. Do not take **lower or higher** doses than the recommended dose.*

In this patient information leaflet:

- 1. What BRONCHOREST® is and what it is used for?**
- 2. What you need to know before you use BRONCHOREST®**
- 3. How to use BRONCHOREST®?**
- 4. Possible side effects**
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1. What BRONCHOREST® is and what it is used for?

BRONCHOREST® is blue-green colored hard gelatin capsules containing 10 mg of montelukast in the form of granular powder and 5 mg of levocetirizine dihydrochloride in the form of tablet.

Levocetirizine is an antihistamine used for the treatment of allergy. Antihistamine drugs eliminate the effect of histamine and eliminate allergy symptoms. Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. By blocking leukotrienes, montelukast improves asthma symptoms and improves allergic rhinitis. Montelukast is not steroid (an organic compound, a type of lipid, associated with cholesterol).

BRONCHOREST® capsules are marketed in Alu/Alu-Aluminum folio blister packaging containing 30 and 90 capsules.

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

BRONCHOREST® is also indicated for the treatment of an antihistamine-resistant skin disease caused by allergy (chronic idiopathic urticaria) in patients 15 years of age and over.

2. What you need to know before you use BRONCHOREST®

DO NOT USE BRONCHOREST® if you have any of the following

If,

- ✓ You are allergic (hypersensitive) to any of the ingredients of BRONCHOREST® or any of the chemical substances called piperazine derivatives,
- ✓ You have severe renal failure (if the clearance rate of creatinine, a substance used to monitor renal functions, from blood is lower than 10 ml/min).

Take special care with BRONCHOREST® if you have any of the following

BRONCHOREST® is not recommended in children aged less than 15 years since the pharmaceutical form of currently available capsules do not allow dose adjustment.

- ✓ Caution is advised if BRONCHOREST® is taken at the same time as alcohol. In sensitive patients, the simultaneous use of cetirizine or levocetirizine and alcohol or other centrally acting agents may have effects on the central nervous system, although the racemate cetirizine has been shown not to increase the effect of alcohol.
- ✓ If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.
- ✓ If your asthma or breathing gets worse, tell your doctor immediately.
- ✓ Efficacy of BRONCHOREST® in the treatment of acute asthma attacks has not been demonstrated. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.
- ✓ It is important that you take all asthma medications prescribed by your doctor. BRONCHOREST® should not be substituted for of other asthma medications your doctor has prescribed for you.
- ✓ Any patient on anti-asthma medicines should be warned that when they 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, they should consult their doctor.
- ✓ If you have asthma and if it gets worse when you take acetyl-salicylic acid (aspirin), you should not take aspirin or other anti-inflammatory medicines also known as non-steroidal anti-inflammatory drugs when using BRONCHOREST®.
- ✓ While taking BRONCHOREST®, if you experience mood changes (such as excessive behavior, aggressive behavior or feelings of hostility, anxiety, depression, loss of communication, dream anomalies, hallucinations, insomnia, restlessness, mobility, sleepwalking, suicidal thoughts and behavior [including suicide attempt) and tremor, inform your doctor as soon as possible.

“Please consult your doctor if these warnings apply to you even at any time in the past.”

Taking BRONCHOREST® with food and drink

You can take BRONCHOREST® with or between meals.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

If you are pregnant or planning to have children, you should consult your doctor before taking BRONCHOREST®. Your doctor will evaluate whether you will use BRONCHOREST® during this period.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Lactation

Before using this medicine consult your doctor or pharmacist.

BRONCHOREST® should not be used during breastfeeding.

Driving and using machinery

Some patients being treated with levocetirizine, which is one of the active ingredients of BRONCHOREST®, experienced somnolence/drowsiness, tiredness and exhaustion. You are advised to use caution and wait until you know how this medicine affects you if you are planning to drive or operate machinery. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

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

Important information about some of the ingredients of BRONCHOREST®

BRONCHOREST® contains lactose. If you have been told by your doctor that you have intolerance to some sugars, please contact your doctor before taking this medicinal product.

Taking with other medicines**Levocetirizine-related interactions**

In sensitive patients, co-administration of cetirizine or levocetirizine with other drugs acting on the central nervous system may have a negative effect on awareness.

Montelukast-related interactions

Some medicines may affect how BRONCHOREST® works, or BRONCHOREST® may affect how other medicines work. Tell your doctor if you are taking the following medicines before starting BRONCHOREST®:

- ✓ phenobarbital (used for treatment of epilepsy)
- ✓ phenytoin (used for treatment of epilepsy)
- ✓ rifampicin (used to treat tuberculosis and some other infections).

- ✓ gemfibrozil (used for treatment of high lipid levels in liquid part except blood cells (plasma))

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. How to use BRONCHOREST®?

Instructions for proper use and dosage/administration frequency:

Recommended dose for adults aged 15 years and over is one capsule daily (5 mg of levocetirizine dihydrochloride and 10 mg of montelukast).

Regarding the duration of treatment, your doctor will determine the type of your allergic rhinitis and decide how long you should take BRONCHOREST®.

Duration of treatment for chronic idiopathic urticaria, which is a skin disorder caused by allergy, may vary from patient to patient; therefore you should follow your doctor's instructions.

Route and method of administration:

BRONCHOREST® must be taken orally, swallowed whole with some water. BRONCHOREST® may be taken with or without food. Capsules should not be chewed or crushed.

Different age groups:

Use in children:

Efficacy and safety in pediatric population below the age of 15 have not been determined.

Use in elderly:

Dose adjustment is not required in elderly patients with normal renal functions.

Special conditions of use:

Renal/Hepatic Failure:

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease. In children the dose will be chosen on the basis of body weight. The dose will be determined by your doctor.

Do not use if you have severe renal failure.

Dose adjustment is not required in patients with mild to moderate hepatic impairment. There is no data available on patients with severe hepatic impairment.

Patients with both liver and kidney failure may be given a lower dose according to the severity of their kidney disease. The dose will be determined by your doctor.

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

If you use more BRONCHOREST[®] than you should:

Somnolence can occur in adults. Children may initially show excitation and restlessness followed by somnolence.

There were no side effects reported in the cases of overdose of montelukast, which is one of the active ingredients of BRONCHOREST[®]. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

If you use more BRONCHOREST[®] than was prescribed, tell your doctor immediately.

If you forget to use BRONCHOREST[®]

Try to take this medicine as prescribed.

If you forget to take a dose, do not take that dose and then continue with the usual schedule.

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

Effects that may occur if you stop taking BRONCHOREST[®]

If you have any further questions on the use of BRONCHOREST[®], ask your doctor or pharmacist.

Stopping the treatment with BRONCHOREST[®] earlier than foreseen should have no detrimental effects. But in this case the symptoms of the disease may just progressively reappear with a severity not higher than the one experienced prior to treatment with BRONCHOREST[®].

4. Possible side effects

Like all medicines, BRONCHOREST[®] may cause side effects in patients sensitive to its ingredients.

Information on levocetirizine, one of the active ingredients of BRONCHOREST[®];

If any of the following reactions happen, stop taking BRONCHOREST[®] and tell your doctor immediately or contact the emergency department at your nearest hospital:

- ✓ Allergic reaction (hypersensitivity reaction) symptoms including swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden fall in blood pressure leading to collapse or shock, which may be fatal
- ✓ Seizure characterized with involuntary muscle contractions (convulsion)
- ✓ Flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash,
- ✓ Abnormal liver function
- ✓ Inflammation of the liver (hepatitis)
- ✓ Palpitation
- ✓ Shortness of breath
- ✓ Visual disturbance
- ✓ Heart rate that exceeds the normal rate (tachycardia)

These are all very serious side effects. If you experience one of them, it means you are severely allergic to BRONCHOREST[®]. You may need urgent medical intervention or to be hospitalized.

All these serious side effects are very rare.

Other side effects:

Other possible side effects are classified according to following categories:

Very common:	Affects at least 1 user in 10.
Common:	Affects 1 to 10 users in 100.
Uncommon:	Affects 1 to 10 users in 1.000.
Rare:	Affects 1 to 10 users in 10.000.
Very rare:	Affects less than 1 user in 10.000.
Not known:	Cannot be estimated from the available data.

Very common:

- ✓ Upper respiratory tract infection

Common

- ✓ Headache
- ✓ Somnolence
- ✓ Dry mouth
- ✓ Tiredness
- ✓ Fatigue
- ✓ Diarrhoea
- ✓ Nausea
- ✓ Vomiting
- ✓ Rash
- ✓ Fever
- ✓ Abdominal pain
- ✓ Elevated liver enzymes

Uncommon

- ✓ Prostration
- ✓ Constipation
- ✓ Indigestion
- ✓ Sleep disturbances
- ✓ Dream abnormalities including nightmares
- ✓ Insomnia
- ✓ Irritability
- ✓ Anxiety
- ✓ Restlessness
- ✓ Aggressive behavior or hostility sensation
- ✓ Sleepwalking
- ✓ Depression
- ✓ Dizziness
- ✓ Drowsiness
- ✓ Tingling
- ✓ Loss of sensation
- ✓ Seizures
- ✓ Nose bleeding
- ✓ Bruising

- ✓ Itching
- ✓ Hives
- ✓ Joint pain
- ✓ Muscle pain including muscle cramps
- ✓ Leg Oedema
- ✓ Abdominal pain
- ✓ Asthenia

Rare

- ✓ Increased bleeding tendency
- ✓ Tremor
- ✓ Palpitation
- ✓ Attention deficit
- ✓ Amnesia

Very rare

- ✓ Hallucination (Hearing or seeing things that are not actually occurring)
- ✓ Suicidal thoughts and behaviors
- ✓ Behavioral changes

Not known

- ✓ Increased appetite
- ✓ Irritability
- ✓ Spasms
- ✓ Drowsiness
- ✓ Fainting
- ✓ Distortion of the sense of taste
- ✓ Visual disturbance
- ✓ Blurred vision
- ✓ Shortness of breath
- ✓ Painful urination
- ✓ Difficult urination
- ✓ Weight increase
- . Oculogyration(involuntary movement of the eyeball in any direction)

These are mild side effects of BRONCHOREST®.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

Reporting side effects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to store BRONCHOREST®?

Store BRONCHOREST® in its original packaging and keep out of the reach and sight of children.

Store BRONCHOREST® at room temperature, below 25°C.

Use in compliance with the expiry date.

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

Marketing Authorization Holder:

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This package leaflet was approved on 17.05.2019.