

PATIENT INFORMATION LEAFLET

CREBROS[®] 5 mg film tablet For oral use

- **Active substance** Each tablet contains 5 mg levocetirizine dihydrochloride.
- **Excipients:** Lactose monohydrate, microcrystalline cellulose, titanium dioxide, povidone K25, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, HPMC, talc and macrogol (PEG 6000).

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 as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital*
- *Strictly follow these instructions. Do not take **lower or higher** doses than the recommended dose*

In this patient information leaflet:

1. **What CREBROS[®] is and what it is used for?**
2. **What you need to know before you use CREBROS[®]**
3. **How to use CREBROS[®]?**
4. **Possible side effects**
5. **How to store CREBROS[®]?**

1. What CREBROS[®] is and what it is used for?

- CREBROS[®] is antihistamine used for the treatment of allergy. Antihistamine drugs destroy the effect of histamine, eliminate the signs of allergy.
- CREBROS[®] is available in blister packaging of 20 and 40 tablets. Tablets are white, oval, convex film coated tablets, with “LS” logo on one side.
- CREBROS[®] is used in children aged 6 years and above and in adults for the treatment of allergic rhinitis (intermittent/persistent or seasonal/perennial) and symptoms (itching, exanthema, redness) related to chronic hives of unknown origin (chronic idiopathic urticaria).
- CREBROS[®] contains lactose monohydrate from bovine origin.

2. What you need to know before you use CREBROS[®]

DO NOT USE CREBROS[®] if you have any of the following

If;

- You are known to be allergic (hypersensitive) to the active substance levocetirizine dihydrochloride or any of the ingredients of CREBROS[®],

- You have severe renal failure (renal failure where your creatinine clearance (clearance of creatinine, a substance used to monitor kidney functions, from blood through kidneys) is below 10 ml/min.).

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

- CREBROS® is not recommended for infants and children less than 6 years.
- CREBROS® contains lactose from bovine origin. You have been told by your doctor that you have intolerance to some sugars (that you are sensitive to this kind of sugar), please contact your doctor before taking this medicinal product.
- Caution is advised if CREBROS® 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.
- Consult your doctor if you are suffering from epilepsy or are at risk of seizures, as CREBROS® can increase the severity of seizures.
- If you are going to be tested for allergies, ask your doctor if you should stop using CREBROS® a few days before the test. This medication can affect your allergy test results.
- 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.

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

Taking CREBROS® with food and drink

You can take CREBROS® with or between meals.

Pregnancy

- *Before using this medicine consult your doctor or pharmacist.*
- CREBROS® should be avoided during pregnancy.
- However you can use if prescribed according to risk/benefit ratio.
- *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.*
- *CREBROS® is not recommended during lactation because cetirizine passes into the breast milk.*

Driving and using machinery

Some patients being treated with CREBROS® experienced drowsiness, tiredness and exhaustion. If you are intending to drive, engage in potentially hazardous activities or use machines you are therefore advised first to wait and observe your response to the medication. 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.

Important information on some excipients present in CREBROS®

CREBROS® contains lactose from bovine origin. 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

In sensitive patients, the simultaneous use of cetirizine or levocetirizine and other centrally acting agents may have effects on the central nervous system.

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 CREBROS®?

Instructions for proper use and dosage/administration frequency:

Always take CREBROS® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- In children aged 6 -12 years: 5 mg (1 film tablet) once a day.
- In adolescents over 12 and in adults: 5 mg (1 film tablet) once a day.
- In the treatment of chronic hives (chronic urticaria), your doctor may increase the dose of CREBROS® up to 20 mg (4 film-coated tablets) per day.

Route and method of administration:

- CREBROS® tablets are for oral use only.
- Film tablet should be swallowed whole with a glass of water. Daily dose should be taken at one time.
- CREBROS® may be taken with or without food.

Different age groups:

In children:

It is not recommended in children under 6 years of age since the film-coated tablets do not allow for dose adaptation.

Elderly:

Dose adjustment is not necessary if renal function is normal.

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.
- Patients who only have impaired liver function should take the usual prescribed dose.
- Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

The duration of treatment with CREBROS® will be determined by your doctor according to the type, duration and nature of your complaints.

Follow these instructions unless otherwise recommended by your doctor.

Do not forget to take your medicine on time.

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

If you use more CREBROS® than you should

If you use more CREBROS® than was prescribed, tell your doctor immediately.

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

If you forget to use CREBROS®

If you forget to take CREBROS®, or if you take a dose lower than that prescribed by your doctor continue with the next dose as usual.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking CREBROS®

Stopping the treatment with CREBROS® 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 CREBROS®. Symptoms can pass spontaneously. In some cases, symptoms may be severe and require resumption of treatment. Symptoms should improve when treatment is restarted.

If you have any further questions for the use of this medicine, talk to a doctor or pharmacist.

4. Possible side effects?

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

If any of the following reactions happen, stop taking CREBROS® 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),
- Abnormal liver function
- Inflammation of the liver (hepatitis)
- Palpitation
- Shortness of breath,
- Visual disturbance
- Heart rate that exceeds the normal rate

These are all very serious side effects.

If you experience one of them, it means you are severely allergic to CREBROS®.

You may need urgent medical intervention or to be hospitalized.

All these serious side effects are very rare.

Very common	: in at least 1 patient of 10.
Common	: in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	: in less than 1 of 1000 patients but more than 1 of 10.000 patients.
Very rare	: in less than 1 of 10.000 patients.
Not known	: Cannot be estimated based on available data

Common:

- Headache
- Somnolence/drowsiness

- Dryness of the mouth
- Tiredness

Uncommon

- Abdominal pain
- Exhaustion

Rare

- Aggressive or extremely anxious behavior
- Hearing or seeing things that are not actually occurring (hallucination)
- Depression
- Recurring thoughts of or preoccupation with suicide
- Nightmares
- Palpitation
- Increase in heart rate
- Insomnia
- An even fatal allergic reaction to the medication

Not known

- Edema
- Severe itching
- Rash
- Hives (swelling, itching and redness of the skin)
- Dizziness
- Numbness
- Fainting
- Tremor
- Skin irritation
- Weight gain
- Muscle ache
- Nausea
- Vomiting
- Diarrhea
- Dysgeusia (distortion of the sense of taste)
- Sensation of rotation or movement
- Blurred vision
- Painful urination
- Inability to completely empty the bladder
- Increased appetite
- Shortness of breath
- Abnormal liver function
- Oculogyration (involuntary movement of the eyeball in any direction)

These are mild side effects of CREBROS®.

If you experience any side effects that are not listed in this leaflet, tell this to your doctor or pharmacist.

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 CREBROS®?

*Store CREBROS® in its original packaging and keep out of the reach and sight of children.
Store below 25°C.*

Use in compliance with the expiry date.

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

Do not use CREBROS® if you notice any defect/damage on the product and/or packaging.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

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