

L-CERITEC FILM COATED TABLET 5MG

Levocetirizine Dihydrochloride (5mg)

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What L-Ceritec is used for

L-Ceritec is used to treat the symptoms of:

- Allergic rhinitis (inflammation of the mucous membrane inside the nose) including persistent allergic rhinitis
- Chronic idiopathic urticaria (a raised, itchy rash of unknown cause)

How L-Ceritec works

L-Ceritec contains the active ingredient levocetirizine dihydrochloride.

L-Ceritec is an anti-allergic medication. It works by blocking a certain natural substance (histamine) that your body makes during allergic reaction.

Before you use L-Ceritec

- When you must not use it

DO NOT take L-Ceritec if you have:

- Allergy (hypersensitive) to the active ingredient levocetirizine dihydrochloride, cetirizine, hydroxyzine, piperazine derivatives or any of the excipients listed contains in the product.
- Severe renal impairment at less than 15 ml/min creatinine clearance.

The use of L-Ceritec tablet is not recommended for infants and children under 6 years.

- Before you start to use it

Tell your doctor or pharmacist if any of the following applies to you:

- If you have difficulties emptying your bladder due to factors such as spinal cord lesion or prostatic hyperplasia (enlargement of the prostate gland).
- If you have been told by your doctor that you have an intolerance to some sugars. This tablet contains lactose.
- If you have epilepsy or you are at risk of convulsions (fits).

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant, trying to get pregnant or breastfeeding. Levocetirizine is excreted in human milk. Talk to your doctor or pharmacist before taking this medicine if you are breastfeeding.

- Taking other medicines

Tell your doctor or pharmacist if you are taking theophylline and ritonavir or any other medicines that you get without a prescription.

How to use L-Ceritec

- How much to use

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

The usual dose is:

- Adults and adolescents 12 years and above: The daily recommended dose is 5mg (1 film coated tablet) once daily.
- Children aged 6 to 12 years: The daily recommended dose is 5mg (1 film coated tablet).

Special dosage instructions for specific populations:

If you have impaired kidney function, you may be given a lower dose according to the severity of your kidney disease, and body weight will be taken into consideration in children.

The dose will be determined by your doctor.

If you have end-stage kidney disease or are undergoing dialysis you must not take L-Ceritec.

No dose adjustment is needed if you have liver impairment alone. However, if you have both liver and kidney impairment, please consult your doctor for dose adjustments.

No dose adjustment is needed in the elderly, provided their kidney function is normal.

- When to use it

L-Ceritec must be taken orally, swallowed whole with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake.

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

- How long to use it

The duration of use of L-Ceritec depends on the type, duration and course of your complaints and is determined by your doctor.

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

- If you forget to use it

If you forget to take L-Ceritec or if you take a dose lower than that prescribed by your doctor, do not take a double dose for a forgotten one. Proceed with administration taking the next dose in time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there

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are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children.

- If you stop taking it

Rarely pruritus (intense itching) may occur if you stop taking L-Ceritec, even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell any doctors, dentist, and pharmacist who treat you that you are taking L-Ceritec.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give L-Ceritec to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Caution is advised if L-Ceritec is taken at the same time as alcohol. In sensitive people, the simultaneous use of cetirizine or levocetirizine with alcohol or other medicines that act on the brain may affect alertness.

Some people on L-Ceritec may experience drowsiness, tiredness and lack of energy.

Although clinical trials have revealed no evidence of impairment in mental alertness, special precautions should be considered if you intend to drive or operate machinery.

Side effects

L-Ceritec may cause potential side effects, such as:

Common (may affect up to 1 in 100 people to less than 1 in 10 people)

Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon (may affect up to 1 in 1000 people to less than 1 in 100 people)

Exhaustion and abdominal pain

Very rare side effects such as palpitations (irregular heartbeat), increased heart rate, seizures, pins and needles sensation, dizziness, syncope (temporary loss of consciousness), tremor, dysgeusia (distortion of the sense of taste), sensation of spinning, visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements), painful urination, incomplete voiding of bladder, oedema (fluid retention), pruritus (intense itchiness) upon discontinuation, rash, urticaria (swelling, redness and itchiness of skin), skin eruption, shortness of breath, increase in weight and appetite, muscle and joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmares, hepatitis, abnormal liver function, vomiting, nausea and diarrhea have also been reported.

Stop taking L-Ceritec and consult your doctor immediately as soon as you experience hypersensitivity or any adverse reactions. Hypersensitivity reaction may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties

(chest tightness or wheezing) hives, anaphylaxis shock which may be fatal.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of L-Ceritec

- Storage

Store below 30°C. Protect from light. Keep out of reach of children. Do not use L-Ceritec after the expiry date stated on the blister and carton.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

A white color, elliptical film coated tablet, one side impressed with 'Y'.



Ingredients

- Active ingredient

Levocetirizine Dihydrochloride

- Inactive ingredients

Microcrystalline Cellulose

Lactose

Colloidal Silicon Dioxide

Magnesium Stearate

Sodium Starch Glycolate

Sodium Stearyl Fumarate

Opadry White (Titanium Dioxide, Polydextrose, Hypromellose, Triacetin and Macrogol).

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Levocetirizine Dihydrochloride (5mg)

Purified Water

- *MAL number(s)*:

MAL26076046AZ

**Manufacturer and Product
Registration Holder**

Y.S.P. Industries (M) Sdn. Bhd.
Lot 3, 5, 7, 12 & 14, Jalan P/7, Section
13, Kawasan Perindustrian Bandar
Baru Bangi, 43000 Kajang, Selangor,
Malaysia.

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