

STADELTINE FILM-COATED TABLET 5 MG

Levocetirizine dihydrochloride 5mg

What is in this leaflet

1. What Stadeltime is used for
2. How Stadeltime works
3. Before you use Stadeltime
4. How to use Stadeltime
5. While you are using Stadeltime
6. Side effects
7. Storage and Disposal of Stadeltime
8. Product description
9. Manufacturer and product registration holder
10. Date of revision
11. Serial number

What Stadeltime is used for

Stadeltime 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 Stadeltime works

Stadeltime contains the active ingredient levocetirizine dihydrochloride. Stadeltime is an antiallergic medication. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

Before you use Stadeltime

- When you must not use it

Do not take Stadeltime

- if you are allergic (hypersensitivity) to the active substance, levocetirizine dihydrochloride, cetirizine, hydroxyzine or to an antihistamine, or any of the other ingredients of Stadeltime (see section **Product Description**).
- if you have a severe kidney impairment with creatinine clearance below 10ml/min.

The use of Stadeltime is not recommended for infants and children under 6 years.

Pregnancy and breastfeeding

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.

- Before you start to use it

Tell your doctor if you have any of the following conditions:

- 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).

- Taking other medicines

Please tell your doctor or pharmacist if you are taking *theophylline* and *ritonavir* or have recently taken any other medicines, including medicines obtained without prescription.

How to use Stadeltime

- How much to use

Always take Stadeltime 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).
- 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 Stadeltime.
- 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

- The film-coated tablet 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 Stadeltime 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 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 Stadeltime 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 nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent attention.

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- 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 Stadeltime, 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 all the doctors, dentists and pharmacists treating you that you are taking Stadeltime.
- 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 Stadeltime to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

- Caution is advised if Stadeltime 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 Stadeltime 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

Stadeltime 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

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 Stadeltime 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, anaphylactic shock which may be fatal.

If any of the side effects gets serious, or if you notice any side effects which are not listed in this leaflet, please 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 npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Stadeltime

- Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date.

Do not store above 30°C.

Keep all medicines out of reach of children.

Do not use Stadeltime if you notice any visible sign of deterioration.

- Disposal

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

Product Description

- What it looks like

Stadeltime appears as white, caplet-shaped, film-coated tablet, biconvex, engraved with “5” on one side and plain on the other side.

- Ingredients

Active ingredient:

Levocetirizine dihydrochloride 5mg

Inactive ingredients:

Microcrystalline cellulose

Lactose monohydrate

Low-substituted hydroxypropyl cellulose

Magnesium stearate

Colloidal anhydrous silica

Hypromellose

Macrogol 6000

Talc

Titanium dioxide

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- MAL No.: MAL22016017AZ

Manufacturer

**STELLAPHARM J.V.CO., LTD –
BRANCH 1**

(A Joint Venture Company of Auxilto
GmbH, Germany)

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Product Registration Holder

Stadpharm Sdn. Bhd.

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