

LAZINE 5MG TABLETS

Levocetirizine dihydrochloride (5mg)

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What LAZINE is used for

LAZINE is used to treat the symptoms of:

- Allergic rhinitis (inflammation of the mucous membrane inside the nose) including persistent allergic rhinitis.
- Long term hives of unknown cause.

How LAZINE works

LAZINE contains the active ingredient levocetirizine dihydrochloride.

LAZINE is an antiallergic medication. It works by blocking a certain natural substance (histamine) that your body makes during allergic reaction.

Before you use LAZINE

-When you must not use it

Do not take LAZINE if you have:

- Allergy (hypersensitivity) to the active ingredient levocetirizine dihydrochloride, cetirizine, piperazine or any of the ingredients listed contained in the product.
- Severe kidney impairment at less than 10 ml/min creatinine clearance.

The use of LAZINE 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.

-Before you start to use it

Tell your doctor if you have been told by your doctor that you have an intolerance to some sugars. This tablet contains lactose.

-Taking other medicines

Tell your doctor or pharmacist if you are taking theophylline (used to treat asthma) or any other medicines including those that you get without a prescription.

How to use LAZINE

-How much to use

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

The usual daily dose for:

- Adults and children aged 6 years old and above: 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 LAZINE.

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.

-How long to use it

The duration of use depends on the type, duration and course of your complaint 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 LAZINE 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 is 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.

While you are using LAZINE

-Things you must do

Tell any doctors, dentist, and pharmacists who treat you that you are taking this medicine.

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

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-Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give LAZINE to anyone else, even if they have the same symptoms or conditions as you.

-Things to be careful of

Caution is advised if LAZINE 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.

In clinical trials, the occurrence of sleepiness has been reported in some people taking cetirizine. So, caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

Side effects

LAZINE may cause potential side effects, such as:

Common

Dry mouth, headache, tiredness, and sleepiness.

Uncommon

Abdominal pain.

Stop taking LAZINE 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, and serious allergic reactions may be fatal.

If any of the side effects get serious, or if you notice any side effects 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 npra.gov.my

[Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of LAZINE

-Storage

Store in a dry place below 25°C and protected from light.

Keep LAZINE and all medicines safely away from children.

Do not use this medicine after the month and year shown by the numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

-Disposal

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

Product Description

-What it looks like

White film coated, scored, round shaped, standard concave tablets, debossed with '161' on one side and 'H' on the other side.

Pack size: 3x10's Aluminium Blister Pack

-Ingredients:

-Active ingredients:

Each film-coated tablet contains Levocetirizine Dihydrochloride (5mg).

-Inactive ingredients:

- Lactose monohydrate
- Microcrystalline cellulose
- Silica, colloidal anhydrous

- Magnesium stearate
- Opadry White YS-1-7003
- Purified Water

-MAL number:

MAL11070006AZ

Manufacturer

Hetero Labs Limited
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I.D.A., Jeedimetla,
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Product Registration Holder

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