

LEVOCETIRIZINE SYRUP

Levocetirizine Dihydrochloride (2.5mg/5ml)

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What LEVOCETIRIZINE is used for

LEVOCETIRIZINE is an anti-allergic agent. It is used to treat symptoms associated with allergic conditions, such as:

- Hay fever
- Year-round allergies such as dust or pet allergies
- Chronic unknown cause of nettle rash

How LEVOCETIRIZINE works

Levocetirizine works by blocking the effects of histamine, which helps to relieve allergic symptoms which can include rashes, sneezing, watery eyes and a runny or blocked nose.

Before you use LEVOCETIRIZINE

- When you must not use it

Hypersensitivity

Do not take LEVOCETIRIZINE if

- You are allergic (hypersensitive) to LEVOCETIRIZINE, or any other related substance, or any of the other ingredients of LEVOCETIRIZINE contains.
- You have been told by your doctor that you have intolerance to some sugars
- use in infants and toddlers aged less than 2 years
- you have end-stage kidney disease

- Before you start use it

Check with your doctor or pharmacist before taking LEVOCETIRIZINE if:

- If you suffer from kidney impairment, you may require a lower dosage and should discuss your situation with your doctor.

Pregnancy and Breast-Feeding

No information is available on the safe use of LEVOCETIRIZINE during pregnancy or breast-feeding. When you are pregnant or breast-feeding you should only use LEVOCETIRIZINE if there is a clear benefit outweighing the possible risks. Your doctor will make this decision for you.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Other medicines may be affected by LEVOCETIRIZINE. It, in turn, may affect how well LEVOCETIRIZINE works.

How to use LEVOCETIRIZINE

Appropriate volume of oral solution should be measured with the oral syringe and poured in a spoon or in a glass of water. The oral solution must be taken orally immediately after dilution.

- How much to use

Always use LEVOCETIRIZINE exactly as your doctor has told you. You should check with your doctor or pharmacist.

The usual dose:

Adults and children 6 years and above
The daily recommended dose of LEVOCETIRIZINE is 5mg daily (10ml of solution).

Children aged 2 to 6 years

The daily recommended dose is 2.5mg to be taken in 2 intakes of 1.25mg (2.5ml of solution twice daily).

Elderly

Adjustments of the dose is recommended in elderly with kidney impairment.

Kidney impairment

Dosing will be adjusted according to kidney function

- When to use it

Use as directed by your doctor or pharmacist. You may take it with or without food.

- How long to use it

Continue taking LEVOCETIRIZINE for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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

Taking too much of this product may cause drowsiness in adults and initially agitation and restlessness confusion, followed by drowsiness in children.

While you are using it –**- Things you must do**

Take your medicine exactly as your doctor has told you.

Consume this medicine orally.

Tell all the doctors, dentists and pharmacists treating you that you are taking LEVOCETIRIZINE.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

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

You should be cautious if you take LEVOCETIRIZINE at the same time as alcohol. In sensitive people the effect of alcohol may be increased or different than expected.

- Things to be careful of***Driving and using machines***

In some people LEVOCETIRIZINE may cause drowsiness, tiredness and exhaustion. If you experience any of these symptoms, then do not drive or operate any machines.

Side effects

Like all medicines, LEVOCETIRIZINE can cause side effects, although not everybody gets them. Adverse events observed in association with the use of LEVOCETIRIZINE are listed below.

Common:

- Fatigue
- Sleepiness
- Headache
- Dry mouth

Uncommon:

- Abnormal physical weakness or lack of energy
- Abdominal pain

Very rare:

- Serious allergic reaction
- Difficulty breathing
- Nausea
- Swelling under the skin
- Skin itching
- Rash
- Weight gain

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of LEVOCETIRIZINE**- Storage**

Keep out of the reach and sight of children.

Store below 30°C. Protect from light and moisture

- Disposal

Medicines should not be disposed of via wastewater or household waste. 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**

Levocetirizine Syrup 2.5mg/5ml is a orange colored syrup pleasantly flavored having a sweet taste and no sediment, filled in amber color bottle, sealed with ROPP cap, labeled and placed in a printed carton.

Ingredients**- Active ingredient(s)**

Levocetirizine Dihydrochloride

- Inactive ingredients

Purified Water, Ordinary Sugar, Methylparaben, Propylparaben, Disodium Edetate, Sodium Citrate, Anhydrous Citric Acid, Sorbitol Solution 70% (Non-Crystallizing), Glycerine, Sunset Yellow FCF Supra, Orange Flavor RS 15215, Hyflosuperpel (Celite)

- MAL number(s):

MAL11030093AZ

Manufacturer

FDC LIMITED,
B-8, MIDC AREA, Waluj
Aurangabad-431 136, Maharashtra,
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Product Registration Holder

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