

LEVOZIN (Levocetirizine Dihydrochloride) Tablets USP 5mg

Consumer Medication Information Leaflet (RiMUP)

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What *LEVOZIN* is used for

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

- chronic unknown cause of hives.
- allergic rhinitis (inflammation of the lining inside the nose)

How *LEVOZIN* works

LEVOZIN helps to relieve allergic symptoms by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

Before you use *LEVOZIN*

- When you must not use it

Do not take *LEVOZIN* if

- You are allergic (hypersensitive) to *LEVOZIN*, or any other related substance, or any of the other ingredients of *LEVOZIN* contains.
- You have severe kidney impairment
- You have been told by your doctor that you have intolerance to some sugars

- Before you start to use it

Check with your doctor or pharmacist before taking *LEVOZIN* :

- 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 *LEVOZIN* during pregnancy or breast-feeding. When you are pregnant or breast-feeding you should only use *LEVOZIN* 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 *LEVOZIN*. They, in turn, may affect how well *LEVOZIN* works.

How to use *LEVOZIN*

- How much to use

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

Adults and adolescents 12 years and above:

The daily recommended dose of *LEVOZIN* is 5mg daily. *Children aged 6 to 12 years:*

The daily recommended dose of *LEVOZIN* is 5mg daily.

Elderly

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

Kidney impairment

Dosing will be adjusted according to kidney function.

LEVOZIN is not recommended in children less than 6 years since the currently available film-coated tablets do not allow dose adaptation.

- When to use it

Use as directed by your doctor or pharmacist. The film-coated tablet must be taken orally, swallowed whole with or without food. It is recommended to take the daily dose in one single intake.

- How long to use it

Continue taking *LEVOZIN* 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 many tablets may cause drowsiness in adults and initially agitation and restlessness, 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 *LEVOZIN*

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 *LEVOZIN* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

You should be cautious if you take *LEVOZIN* at the same time as alcohol. In sensitive people, may cause additional reductions in alertness and impairment of performance.

Driving and using machines

Do not exceed the recommended dose and you have to take into account of how this medicine will affect you if you intend to drive, engage in potentially hazardous activities or operate machinery.

Side effects

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

Common:

- Sleepiness
- Headache
- Dry mouth
- Tiredness

Less common:

- Feeling of weakness

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 visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problem/Side Effect/ AEFI / Vaccine Safety).

Storage and Disposal of LEVOZIN

- Storage

Keep out of the reach and sight of children.

Store in a dry place below 25 °C.

Protect from light

- 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

Yellow coloured circular, biconvex film coated tablets plain on both sides.

- Ingredients

- Active ingredient(s)

Levocetirizine Dihydrochloride

- Inactive ingredients

Lactose, microcrystalline cellulose, isopropyl alcohol, croscarmellose sodium, magnesium stearate, hydroxypropyl methylcellulose, colloidal silicon dioxide, Polyvinyl Pyrolidone (Povidone K-30), Titanium Dioxide, Polyethylene Glycol 400, Talc, Quinoline yellow, Methylene Chloride.

- MAL number

MAL10100016AZ

Manufacturer

FDC Limited,
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Product Registration Holder

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Date of revision

13/07/2022

Serial Number:

NPRA(R4/1)231017/00276