

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

LEVIZAL 5 mg (film-coated tablets)

Levocetirizine dihydrochloride

Contains sugar: Lactose monohydrate 64 mg

Read all of this leaflet carefully because it contains important information for you.

LEVIZAL 5 mg is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use LEVIZAL 5 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LEVIZAL 5 mg with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What LEVIZAL 5 mg is and what it is used for
2. What you need to know before you take LEVIZAL 5 mg
3. How to take LEVIZAL 5 mg
4. Possible side effects
5. How to store LEVIZAL 5 mg
6. Contents of the pack and other information

1. What LEVIZAL 5 mg is and what it is used for

The active ingredient, levocetirizine dihydrochloride, is an antihistamine for systemic use.

LEVIZAL 5 mg is used for relief of symptoms associated with:

- Allergic rhinitis (hay fever) - seasonal allergic rhinitis and allergic rhinitis lasts throughout the year.
- Chronic idiopathic urticaria (also called hives or nettle rash for which the cause is unknown).

2. What you need to know before you take LEVIZAL 5 mg.

Do not take LEVIZAL 5 mg:

- if you or your child is allergic (hypersensitive) to cetirizine, to hydroxyzine, to any piperazine derivative or to any of the inactive ingredients of LEVIZAL 5 mg (Listed in section 6).
- if you or your child has severe impairment of kidney function (creatinine clearance less than 10 ml/min) and patients undergoing dialysis.
- if your child is less than two years old, they must not take LEVIZAL 5 mg.
- if you are pregnant or breastfeeding your baby (see “Pregnancy, breastfeeding and fertility”)

Warnings and precautions

Take special care with LEVIZAL 5 mg:

- if you drink alcohol while taking LEVIZAL 5 mg (see “Taking LEVIZAL 5 mg with food, drink and alcohol”).
- if you or your child has kidney problems (see “Do not take LEVIZAL 5 mg “and section 3).
- If you or your child is unable to empty your bladder completely (with conditions such as spinal cord injury or an enlarged prostate), as LEVIZAL 5 mg may make it more difficult for you to empty your bladder.

- If you suffer from epilepsy (fits) LEVIZAL 5 mg may make your condition worse
- Allergy skin tests won't work properly if you've taken antihistamines, so you need to stop taking them for at least 3 days before the test.
- When you stop taking LEVIZAL 5 mg, you might experience itching (even if you didn't have it before starting the medicine). This usually goes away on its own, but in some cases, the itching can be quite strong and may require you to start taking the medicine again. The itching should stop once the treatment is restarted.
- There isn't enough information to show that LEVIZAL 5 mg is safe or effective for babies and children younger than 2 years old, so it's not recommended for them.

Children and adolescents:

Children younger than 6 years should not take the film-coated tablet form of LEVIZAL 5 mg because the tablet does not allow the dose to be adjusted properly for their age.

Other medicines with LEVIZAL 5 mg:

Always tell your healthcare professional if you or your child is taking any other medicine (This includes complementary or traditional medicines).

There haven't been any specific studies to see how LEVIZAL 5 mg interacts with other medicines that affect certain liver enzymes (called CYP3A4 inducers). However, similar medicines like cetirizine have been tested with other common drugs such as ketoconazole, erythromycin, azithromycin, cimetidine, pseudoephedrine, glipizide, and diazepam. These studies showed no harmful or serious interactions when taken together.

The following medicine may have an interaction with LEVIZAL 5 mg.

- Theophylline (a medicine used in the treatment of asthma and other lung diseases).

- Ritonavir (a medicine used in the treatment of HIV/AIDS).
- Medicines that affect the functioning of the brain and nervous system such as sleeping tablets or tablets used for anxiety.

You must tell your doctor that you or your child is taking LEVIZAL 5 mg before you go for an allergy skin test, as you must stop taking LEVIZAL 5 mg several days before you go for the skin test.

LEVIZAL 5 mg with food and drink and alcohol:

LEVIZAL 5 mg usually does not make you sleepy, but in a small number of people it may cause sleepiness. This effect may be worsened if you take LEVIZAL 5 mg together with alcohol.

It is advisable to avoid drinking alcohol while taking LEVIZAL 5 mg.

You may take LEVIZAL 5 mg with or without food. Swallow the tablet with a sufficient quantity of liquid.

Pregnancy, breastfeeding and fertility

You must not take LEVIZAL 5 mg if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine

Driving and using machines:

LEVIZAL 5 mg may cause sleepiness, tiredness, weakness or blurred vision. Use caution when driving, performing dangerous activities or operating machinery until you know how LEVIZAL 5 mg affects you.

It is not always possible to predict to what extent LEVIZAL 5 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LEVIZAL 5 mg affects them.

LEVIZAL 5 mg contains Lactose Monohydrate

LEVIZAL 5 mg contains lactose monohydrate. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not LEVIZAL 5 mg.

3. How to take LEVIZAL 5 mg

Do not share LEVIZAL 5 mg with any other person.

Always take LEVIZAL 5 mg exactly as described in this leaflet or as your doctor or pharmacist have told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults and adolescents 12 years of age and older:

The daily recommended dose is one 5 mg tablet.

Elderly:

Adjustment of the dose is recommended in elderly patients with renal impairment.

Children aged 6 to 12 years:

The daily recommended dose is one 5 mg tablet.

Children younger than 6 years old:

LEVIZAL 5 mg must not be given to infants and toddlers less than 2 years old (see section 2: Do not take LEVIZAL 5 mg")

The use of LEVIZAL 5 mg is not recommended in children aged between 2 and 6 years old since the dosage for the tablet formulation cannot be adapted for this age group.

Renal impairment:

If you or your child has impaired kidney function, you may have to take a lower dose according to the severity of your kidney disease. Your doctor will determine the dose you must take.

You or your child must not take LEVIZAL 5 mg if you have severe impairment of your kidney function (see section 2: Do not take LEVIZAL 5 mg")

You must consult your doctor if you or your child has impaired kidney function before you start taking LEVIZAL 5 mg.

Liver impairment:

If you or your child only has impaired liver function, you may take the usual prescribed dose.

If you or your child has both impaired liver and kidney function, you may have to take a lower dose depending on the severity of the kidney disease. Your doctor will determine the dose you must take.

You must consult your doctor if you or your child has impaired kidney function before you start taking LEVIZAL 5 mg.

Duration of use:

The duration of use depends on the frequency of your symptoms.

Please consult your doctor and pharmacist on how long you must take LEVIZAL.

Your doctor or pharmacist will tell you how long your treatment with LEVIZAL 5 mg will last.

If you have the impression that the effect of LEVIZAL 5 mg is too strong or too weak, tell your doctor or pharmacist.

Take the tablet by mouth with a sufficient quantity of liquid (e.g. one glass of water).

LEVIZAL 5 mg can be taken with or without food.

It is recommended to take the daily dose in one single intake.

If you take more LEVIZAL 5 mg than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

If you forget to take LEVIZAL 5 mg:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your tablet at the usual time. Do not take a double dose to make up for missed individual doses.

If you stop taking LEVIZAL 5 mg

If you stop taking LEVIZAL 5 mg, you may experience itchy skin (pruritus).

4. Possible side effects

LEVIZAL 5 mg can have side effects.

Not all side effects reported for LEVIZAL 5 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LEVIZAL 5 mg please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking LEVIZAL 5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LEVIZAL 5 mg. You may need urgent medical attention or hospitalisation. The frequency of these very serious side effects is not known.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Convulsions, fits or seizures.
- Changes in the way your heart beat (fast, quivering or irregular heartbeats).
- Yellowing of the skin and eyes, nausea, vomiting, stomach pain and discomfort, loss of appetite, generally feeling unwell, fever, itching, light coloured stools and dark coloured urine. These symptoms might be an indication of a liver disease.
- Having thoughts about suicide.

These are all serious side effects. You may need urgent medical attention. The frequency of these serious side effects is not known.

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- Sleep disorders.
- Sleepiness or drowsiness.
- Headache.
- Dry mouth.
- Diarrhoea.
- Constipation.
- Fatigue.

Less frequent side effects:

- Nausea
- Stomach pain or discomfort.
- Involuntary urination (enuresis).
- Unusual tiredness or weakness.
- Generally feeling unwell.

Side effects for which the frequency is not known:

- Changes in the number of different cells in your blood which may present as tiredness, new infections, fever and easy bruising or bleeding.
- Increase in appetite.
- Weight increase.
- Aggression and agitation.
- Hallucinations (feeling, seeing or hearing things that are not there).
- Depression (feeling sad and unworthy).
- Confusion.
- Vomiting

- Having trouble sleeping, nightmares.
- Tingling, numbness or pins and needles in the hands and feet.
- Dizziness (spinning sensation) or fainting.
- Movement disorders such as tremors, unusual muscle tone causing distortion of the body or rapid, repetitive and involuntary contractions of a muscle.
- Distortion of the sense of taste.
- Visual disturbances or blurred vision.
- Uncontrolled circular movements of the eyeball (oculogyration).
- Whistling or ringing sound in the ears.
- Inflammation of the back of the throat causing a sore throat and discomfort when swallowing.
- Hair loss.
- Muscle or joint pain.
- Painful urination or not being able to empty your bladder completely.
- Sweating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LEVIZAL 5 mg.

5. How to store LEVIZAL 5 mg

Store at or below 25 °C. Protect from light and moisture.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Store all medicines out of reach of children.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information.

What LEVIZAL 5 mg contains:

Active ingredient:

Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.

Inactive ingredients:

Tablet core: Lactose monohydrate, magnesium stearate and microcrystalline cellulose.

Film-coating: Opadry White containing hypromellose, macrogol 400 and titanium dioxide.

Contains sugar (lactose monohydrate).

What LEVIZAL 5 mg looks like and contents of the pack

White to off-white, oval, biconvex tablets. The tablets are debossed with 'L9CZ' on one side and '5' on the other side.

LEVIZAL 5 mg is packed into:

- Transparent or white opaque PVC/PVDC: Al blisters or oPA/Al/PVC: Al blisters

Each blister strip contains 7 or 10 tablets. The blister strips are packed in an outer cardboard carton with pack sizes of 14, 28 or 30 tablets.

Holder of Certificate of Registration.

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Access to the corresponding Professional Information.

www.trinitypharma.co.za