

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

CETIZAL 5 TABLETS 5 mg film-coated tablets

Levocetirizine dihydrochloride.

Contains sugar: Lactose anhydrous (63,5 mg per tablet).

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

CETIZAL 5 TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CETIZAL 5 TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CETIZAL 5 TABLETS 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 CETIZAL 5 TABLETS is and what it is used for
2. What you need to know before you take CETIZAL 5 TABLETS
3. How to take CETIZAL 5 TABLETS
4. Possible side effects
5. How to store CETIZAL 5 TABLETS
6. Contents of the pack and other information

1. What CETIZAL 5 TABLETS is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of CETIZAL 5 TABLETS.

CETIZAL 5 TABLETS is an antihistamine for systemic use.

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It is used for the treatment of signs of illness (symptoms) associated with:

- allergic rhinitis (including persistent allergic rhinitis);
- chronic nettle rash of unknown origin (chronic idiopathic urticaria).

2. What you need to know before you take CETIZAL 5 TABLETS

Do not take CETIZAL 5 TABLETS:

- if you are hypersensitive (allergic) to levocetirizine dihydrochloride, to any piperazine derivative or any of the other ingredients of CETIZAL 5 TABLETS (listed in section 6).
- if you or your child have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 mL/min).
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Talk to your doctor or pharmacist before taking CETIZAL 5 TABLETS. Take special care with CETIZAL 5 TABLETS:

If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.

If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of CETIZAL 5 TABLETS may cause seizure aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking CETIZAL 5 TABLETS for several days before testing. CETIZAL 5 TABLETS may affect your allergy test results.

Children

The use of CETIZAL 5 TABLETS is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

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Other medicines and CETIZAL 5 TABLETS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

CETIZAL 5 TABLETS with food, drink and alcohol

Caution is advised if CETIZAL 5 TABLETS is taken at the same time as alcohol or other medicines acting on the brain. In sensitive patients, the concurrent administration of CETIZAL 5 TABLETS and alcohol or other medicines acting on the brain may cause additional reductions in alertness and impairment of performance.

CETIZAL 5 TABLETS can be taken with or without food.

Pregnancy and breastfeeding

You should not take CETIZAL 5 TABLETS 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

It is not always possible to predict to what extent CETIZAL 5 TABLETS 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 CETIZAL 5 TABLETS affects them.

Some patients being treated with CETIZAL 5 TABLETS may experience somnolence/drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery until you know how this medicine affects you. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

CETIZAL 5 TABLETS contains lactose

CETIZAL 5 TABLETS contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CETIZAL 5 TABLETS.

3. How to take CETIZAL 5 TABLETS

Do not share medicines prescribed for you with any other person.

Always take CETIZAL 5 TABLETS exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults or children aged 6 years and older

The daily recommended dose is one tablet. The tablets should be swallowed whole with water and may be taken with or without food.

If you take more CETIZAL 5 TABLETS than you should

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

Symptoms of overdose may include:

- sleepiness can occur in adults,
- children may initially show a sense of excitation and restlessness followed by somnolence.

If you forget to take CETIZAL 5 TABLETS

Do not take a double dose to make up for forgotten individual doses, just continue taking the amounts stated in the dosage instructions.

If you stop taking CETIZAL 5 TABLETS

Stopping treatment with CETIZAL 5 TABLETS earlier than foreseen should have no detrimental

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effects. However, less frequently pruritus (intense itching) may occur if you stop taking CETIZAL 5 TABLETS 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

CETIZAL 5 TABLETS can have side effects.

Not all side effects reported for CETIZAL 5 TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CETIZAL 5 TABLETS, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CETIZAL 5 TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dry mouth;
- headache;

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- tiredness;
- somnolence/drowsiness.

Less frequent side effects:

- exhaustion;
- abdominal pain.

Side effects with frequency unknown:

- palpitations, increased heart rate;
- fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement;
- visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements);
- painful or difficult urination, inability to completely empty the bladder, oedema;
- pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption;
- shortness of breath;
- weight increase, muscular pain, joint pain, aggressive or agitated behaviour;
- hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmare;
- hepatitis, abnormal liver function;
- vomiting, increased appetite, nausea, diarrhoea;
- pruritus (intense itching) upon discontinuation.

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

Reporting of side effects

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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. Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email:

pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

By reporting side effects, you can help provide more information on the safety of CETIZAL 5 TABLETS.

5. How to store CETIZAL 5 TABLETS

- Store at or below 25 °C.
- Keep the tablets in the original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or blister strips.
- 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 CETIZAL 5 TABLETS contains

The active substance in CETIZAL 5 TABLETS is levocetirizine dihydrochloride.

Each tablet contains 5 mg levocetirizine dihydrochloride.

The other ingredients are colloidal silica dioxide, hypromellose (E464), lactose anhydrous, magnesium stearate (E572), microcrystalline cellulose (E460a), polyethylene glycol (E1521), polysorbate 80 (E433) and titanium dioxide (E171).

What CETIZAL 5 TABLETS looks like and contents of the pack

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White, oval, film-coated tablets with 'S' debossed on one side and break line on the other side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

HDPE bottle

White, opaque HDPE bottle with a white, ribbed polypropylene child-resistant screwcap, induction seal and silica gel desiccant.

Pack size: 30, 90 or 100 tablets.

White, opaque HDPE bottle with a white, ribbed polypropylene screwcap, induction seal and silica gel desiccant.

Pack size: 100 or 1 000 tablets.

Blister pack

Aluminium PVC Blister pack of 10 Tablets. 1 strip (10 tablets) or 3 strips (30 tablets) are packed into carton.

Pack size: 10 or 30 tablets.

Holder of certificate of registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext.1, Roodepoort

Johannesburg

1724

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Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: <https://sunpharma.com/south-africa-products/>

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