

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Cetizal 5
Dosage form: Film-coated tablets
Strength Valaciclovir hydrochloride equivalent to valaciclovir 500 mg/tablet

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

CETIZAL 5 Film-coated Tablets

Levocetirizine dihydrochloride

Contains sugar: Lactose monohydrate 65,71 mg.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CETIZAL 5 with any other person.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

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

CETIZAL 5 belongs to a group of medicines called antihistamines. CETIZAL 5 is used to relieve symptoms like sneezing, itchy, runny nose, and itchy, red and watery eyes associated with hay fever (seasonal or persistent allergic rhinitis).

CETIZAL 5 is also used to relieve symptoms such as swelling, itching and redness associated with an allergic skin condition known as chronic idiopathic urticaria.

Amended proposed patient information leaflet Type IA _{IN} – C.I.0.1; Type IA _{IN} /IB – C.I.0.2.a/b; Type IB- C.1.2a	Version: Clean Copy
Date of Submission: 7 March 2022- Approved-04-05-2022	Page 1 of 7

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Cetizal 5
Dosage form: Film-coated tablets
Strength Valaciclovir hydrochloride equivalent to valaciclovir 500 mg/tablet

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

Do not take CETIZAL 5:

- If you are hypersensitive (allergic) to levocetirizine, similar antihistamines or any of the other ingredients of CETIZAL 5 (listed in section 6).
- If you have end stage kidney disease (severe renal failure with creatinine clearance below 10 mL/min).
- If you are pregnant, planning to become pregnant or breastfeeding.
- The use of CETIZAL 5 is not recommended for infants and children under 2 years of age.

Warnings and precautions

Take special care with CETIZAL 5:

- Caution is advised if CETIZAL 5 is taken at the same time as alcohol or other agents acting on the brain. In some patients, the concurrent administration of CETIZAL 5 and alcohol or other agents acting on the brain may cause sedation.
- If you have liver or kidney problems.
- 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.

Children

This formulation of CETIZAL 5 is not suitable for children aged 2 – 6 years as no adjusted dosage is possible with CETIZAL 5 which is a film-coated tablet. CETIZAL 5 is therefore not recommended for this age group.

Other medicines and CETIZAL 5

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

Especially tell your doctor or pharmacist if you take:

- Alcohol (large amounts).
- Nervous system depressants (such as tranquilizers or sedatives).
- Theophylline (used to treat lung diseases such as asthma, bronchitis and emphysema).
- Ritonavir (medicine used in the treatment of HIV).

CETIZAL 5 with food and drink

CETIZAL 5 tablets may be taken with or without a meal (see section 3).

Amended proposed patient information leaflet Type IA _{IN} – C.I.0.1; Type IA _{IN} /IB – C.I.0.2.a/b; Type IB- C.1.2a	Version: Clean Copy
Date of Submission: 7 March 2022- Approved-04-05-2022	Page 2 of 7

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Cetizal 5
Dosage form: Film-coated tablets
Strength Valaciclovir hydrochloride equivalent to valaciclovir 500 mg/tablet

Caution is advised if CETIZAL 5 is taken at the same time as alcohol.

Pregnancy and breastfeeding

The use of CETIZAL 5 during pregnancy is contraindicated as the safety during pregnancy has not been established.

Do not take CETIZAL 5 if you are breastfeeding as the active ingredient is excreted in breast milk.

If you are pregnant or breastfeeding your baby, 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

CETIZAL 5 may make you feel sleepy, tired or exhausted. If you are intending to drive, engage in potentially hazardous activities or use machines, you are advised first to wait and observe your response to CETIZAL 5.

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

CETIZAL 5 contains lactose monohydrate

CETIZAL 5 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take CETIZAL 5

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

Always take CETIZAL 5 exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose for adults and children over 6 years of age is one tablet daily.

CETIZAL 5 is not recommended for children under 6 years of age.

The tablets should be swallowed whole with water and may be taken with or without food.

Duration of treatment

The duration of use depends on the type, duration and course of your complaints and is determined by your doctor or pharmacist.

If you take more CETIZAL 5 than you should

Amended proposed patient information leaflet Type IA _{IN} – C.1.0.1; Type IA _{IN} /IB – C.1.0.2.a/b; Type IB- C.1.2a	Version: Clean Copy
Date of Submission: 7 March 2022- Approved-04-05-2022	Page 3 of 7

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Cetizal 5
Dosage form: Film-coated tablets
Strength Valaciclovir hydrochloride equivalent to valaciclovir 500 mg/tablet

An overdose may cause drowsiness in adults. Children may initially show excitation and restlessness followed by somnolence.

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

If you forget to take CETIZAL 5

Do not take / receive a double dose to make up for forgotten individual doses.

4 Possible side effects

CETIZAL 5 can have side effects.

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

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

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of the face, lips, tongue, throat, hands/ feet.

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

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

yellowing of the skin and eyes, dark urine, weakness and tiredness which may be symptoms of liver problems (hepatitis),

syncope (fainting),

recurring thoughts of or preoccupation with suicide,

changes in the way your heart beats, for example, if you notice it beating faster,

convulsions

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- headache,

Amended proposed patient information leaflet Type IA _{IN} – C.I.0.1; Type IA _{IN} /IB – C.I.0.2.a/b; Type IB- C.1.2a	Version: Clean Copy
Date of Submission: 7 March 2022- Approved-04-05-2022	Page 4 of 7

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Cetizal 5
Dosage form: Film-coated tablets
Strength Valaciclovir hydrochloride equivalent to valaciclovir 500 mg/tablet

- sleepiness,
- tiredness,
- dry mouth,
- sleep disorders,
- diarrhoea,
- constipation
- vomiting,

Less frequent side effects

- nausea,
- gastrointestinal discomfort, abdominal pain
- A general feeling of being unwell.

Frequency unknown

- visual disturbances
- muscular pain
- aggressive or agitated behaviour
- hallucination
- depression
- abnormal liver function,
- dizziness
- tremor
- dysgeusia (distortion of sense of taste).
- sensation of rotation or movement.
- pins and needles
- painful or difficult urination.
- inability to completely empty the bladder.
- oedema (swelling).
- weight increase
- joint pain,

Amended proposed patient information leaflet Type IA _{IN} – C.1.0.1; Type IA _{IN} /IB – C.1.0.2.a/b; Type IB- C.1.2a	Version: Clean Copy
Date of Submission: 7 March 2022- Approved-04-05-2022	Page 5 of 7

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Cetizal 5
Dosage form: Film-coated tablets
Strength Valaciclovir hydrochloride equivalent to valaciclovir 500 mg/tablet

- insomnia,
- increased appetite,
- blurred vision.

If you are concerned about any side effects, talk to your doctor.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CETIZAL 5.

5. How to store CETIZAL 5

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package/ container.
- Keep the container in the outer carton.
- Keep the container tightly closed.
- Do not remove the blister strips from the cartons until required for use.
- Protect from light/ moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/ carton/ bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CETIZAL 5 contains

The active substance is levocetirizine dihydrochloride 5 mg.

The other ingredients are:

Tablet core: Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

Amended proposed patient information leaflet Type IA _{IN} – C.I.0.1; Type IA _{IN} /IB – C.I.0.2.a/b; Type IB- C.1.2a	Version: Clean Copy
Date of Submission: 7 March 2022- Approved-04-05-2022	Page 6 of 7

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Cetizal 5
Dosage form: Film-coated tablets
Strength Valaciclovir hydrochloride equivalent to valaciclovir 500 mg/tablet

Film-coat: Titanium dioxide, hypromellose, macrogol/polyethylene glycol 400, polysorbate 80.

What CETIZAL 5 looks like and contents of the pack

White, film-coated, scored, round, biconvex tablets debossed with '161' on one side and 'H' on other side.

White opaque HDPE container with white opaque polypropylene, plastic cap containing 30 or 180 tablets.

Cold form blister pack comprising of cold formable laminated film with a backing of hard tempered plain silver aluminium foil containing 10 tablets.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd
a Sun Pharma Company
14 Lautre Road, Stormill Ext 1
Roodepoort, 1724
South Africa

This leaflet was last revised in

04 May 2022

Registration number

46/5.7.1/0329

Amended proposed patient information leaflet Type IA _{IN} – C.1.0.1; Type IA _{IN} /IB – C.1.0.2.a/b; Type IB- C.1.2a	Version: Clean Copy
Date of Submission: 7 March 2022- Approved-04-05-2022	Page 7 of 7