Date of submission: 21 May 2025

Proposed Patient Information Leaflet for CETIZAL 5 TABLETS

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.

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.

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 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;
- 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

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

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

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1724

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44/5.7.1/0017

Pasiëntinligtingstuk vir CETIZAL 5 TABLETS

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S1

CETIZAL 5 TABLETS, 5 mg filmbedekte tablette

Levosetirisiendihidrochloried.

Bevat suiker: Laktose (63,5 mg per tablet).

Lees die hele inligtingstuk noukeurig deur omdat dit belangrike inligting vir jou bevat

CETIZAL 5 TABLETS is vir jou beskikbaar sonder ‘n dokter se voorskrif om ‘n ligte siektetoestand te behandel. Jy moet CETIZAL 5 TABLETS nogtans versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees..
- Moenie CETIZAL 5 TABLETS met enige ander persoon deel nie.
- Vra jou gesondheidsorgvoorsienier of apteker indien jy meer inligting of advies benodig.
- Jy moet jou dokter raadpleeg as jou simptome vererger of nie binner 5 dae verbeter nie.

Wat is in hierdie inligtingstuk

1. Wat is CETIZAL 5 TABLETS en waarvoor word dit gebruik
2. Wat jy behoort te weet voordat jy CETIZAL 5 TABLETS neem
3. Hoe om CETIZAL 5 TABLETS te neem
4. Moontlike newe-effekte
5. Hoe om CETIZAL 5 TABLETS te bewaar

6. Inhoud van die verpakking en ander inligting

1. Wat is CETIZAL 5 TABLETS en waarvoor word dit gebruik

Levosetirisiendihidrochloried is die aktiewe bestanddeel van CETIZAL 5 TABLETS.

CETIZAL 5 TABLETS is ‘n antihistamien vir sistemiese gebruik.

Dit word gebruik vir die behandeling van tekens van siekte (simptome) geassosieer met:

- allergiese rinitis (insluitende hardnekkige allergiese rinitis);
- chroniese netelroos van onbekende oorsprong (chroniese idiopatiese urtikarie).

2. Wat jy behoort te weet voordat jy CETIZAL 5 TABLETS neem

Moenie CETIZAL 5 TABLETS neem nie:

- as jy hipersensitief (allergies) is vir levosetirisiendihidrochloried, vir enige piperasienderivaat of enige van die ander bestanddele van CETIZAL 5 TABLETS (gelys in afdeling 6).
- as jy of jou kind ‘n ernstige inkorting van die nierfunksie het (ernstige nierversaking met kreatinienopruiming onder 10 mL/min).
- as jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Praat met jou dokter of apteker voordat jy CETIZAL 5 TABLETS neem.

Tref spesiale voorsorg met CETIZAL 5 TABLETS:

As jy geneig is om nie instaat te wees om jou blaas te ledig nie (met toestande soos spinaalkoordbesering of vergrootte prostaat), moet jy asseblief jou dokter nader vir advies.

As jy aan epilepsie ly of as daar ‘n risiko van konvulsies is, moet jy asseblief jou dokter raadpleeg vir advies, aangesien die gebruik van CETIZAL 5 TABLETS die verergering van toevalle kan veroorsaak.

As jy geskeduleer is vir allergie toetsing, moet jy jou dokter vra of jy moet ophou om CETIZAL 5

TABLETS te neem vir verskeie dae voor die toetsing. CETIZAL 5 TABLETS kan jou allergie toetsresultate affekteer.

Kinders

Die gebruik van CETIZAL 5 TABLETS word nie aanbeveel vir kinders onder 6 jaar nie, aangesien die filmbedekte tablette nie voorsiening maak vir dosisaanpassing nie.

Ander medisyne en CETIZAL 5 TABLETS

Lig jou gesondheidsorgvoorsiener altyd in as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

CETIZAL 5 TABLETS saam met voedsel, drinkgoed en alkohol

Versigtigheid word aangeraai as CETIZAL 5 TABLETS op dieselfde tyd as alkohol of ander medisyne wat op die brein inwerk, gebruik word. By sensitiewe pasiënte, kan die gelyktydige toediening van CETIZAL 5 TABLETS **e**n alkohol of ander medisyne wat op die brein inwerk, afnames in waaksaamheid en belemmering van werkverrigting veroorsaak.
CETIZAL 5 TABLETS kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding

Jy moenie CETIZAL 5 TABLETS neem as jy swanger is of jou baba borsvoed nie.
As jy swanger is of borsvoed, dink dat jy swanger mag wees of beplan om ‘n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgvoorsiener raadpleeg vir advies voordat jy hierdie medisyne neem.

Bestuur en gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel tot watter mate CETIZAL 5 TABLETS mag inmeng met die

daaglikse aktiwiteite van ‘n pasiënt nie. Pasiënte moet seker maak dat hulle nie betrokke raak in bogenoemde aktiwiteite totdat hulle weet tot watter mate CETIZAL 5 TABLETS hulle affekteer nie.

Sommige pasiënte wat met CETIZAL 5 TABLETS behandel word, mag slaperigheid/lomerigheid, moegheid en uitputting ervaar. Wees versigtig wanneer jy bestuur of masjinerie gebruik totdat jy weet hoe hierdie medisyne jou affekteer. Spesiale toetse het egter aangedui dat geen inkorting van verstandelike waaksaamheid, die vermoë om te reageer of die vermoë om te bestuur by gesonde toetspersone voorgekom het nadat levosetirisien teen die aanbevole dosis geneem is nie.

CETIZAL 5 TABLETS bevat laktose

CETIZAL 5 TABLETS bevat ‘n suiker wat laktose genoem word. As jou dokter jou aangesê het dat jy ‘n onverdraagsaamheid teenoor sekere suikers het, moet jy jou dokter raadpleeg voordat jy CETIZAL 5 TABLETS neem.

3. Hoe om CETIZAL 5 TABLETS te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem CETIZAL 5 TABLETS altyd presies soos wat dit beskryf is in hierdie inligtingstuk of soos wat jou dokter of apteker vir jou gesê het. Kontroleer met jou dokter of apteker as jy onseker is.

Volwassenes of kinders 6-jarige ouderdom en ouer

Die aanbevole daaglikse dosis is een tablet. Die tablette moet heel met water ingesluk word en kan met of sonder voedsel geneem word.

As jy meer CETIZAL 5 TABLETS geneem het as wat jy behoort te neem

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar

is nie, kontak die naaste hospitaal of gifbeheersentrum.

Simptome van oordosering kan insluit:

- slaperigheid kan voorkom by volwassenes,
- kinders kan aanvanklik ‘n gevoel van prikkelbaarheid en rusteloosheid toon, gevolg deur slaperigheid.

As jy vergeet het om CETIZAL 5 TABLETS te neem

Moenie ‘n dubbele dosis neem om te vergoed vir die individuele dosisse wat jy vergeet het nie, gaan net voort om die hoeveelheid soos in die dosisaanwysings te gebruik.

As jy ophou om CETIZAL 5 TABLETS te neem

Staking van behandeling met CETIZAL 5 TABLETS vroeër as voorsien sal geen nadelige effekte hê nie. Minder dikwelse pruritus (intense gejeuk) mag egter voorkom as jy ophou om CETIZAL 5 TABLETS te neem selfs as daardie simptome nie teenwoordig was voordat met behandeling begin is nie. Die simptome kan spontaan opklaar. In sommige gevalle, kan die simptome intens wees en mag dit nodig wees om behandeling te hervat. Die simptome behoort op te klaar wanneer behandeling hervat word.

Raadpleeg jou dokter of apteker as jy enige verdere vrae het oor die gebruik van die medisyne.

4. Moontlike newe-effekte

CETIZAL 5 TABLETS kan newe-effekte hê.

Nie alle newe-effekte wat vir CETIZAL 5 TABLETS aangemeld is, is in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy CETIZAL 5 TABLETS neem, raadpleeg asseblief jou gesondheidsorgvoorsiener vir advies.

Indien enige van die volgende gebeur, staak die gebruik van CETIZAL 5 TABLETS en lig jou

dokter dadelik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat moeilike sluk of asemhaling mag veroorsaak;
- uitslag of gejeuk;
- floute.

Hierdie is almal baie ernstige newe-effekte. As jy hulle het, kon jy ‘n ernstige reaksie teenoor CETIZAL 5 TABLETS gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- droë mond;
- hoofpyn;
- moegheid;
- slaperigheid/lomerigheid.

Minder dikwelse newe-effekte:

- uitputting;
- abdominale pyn.

Newe-effekte met onbekende voorkoms:

- palpitasies, verhoogde hartritme;
- toevalle, naalde-en-spelde, duiseligheid, sinkopee, bewerigheid, disgeusie (verdraaiing van die smaaksensasie), sensasie van rotasie of beweging;
- visuele versteurings, dowwe visie, oculogirasie (oë het ongekontrolleerde sirkelvormige bewegings);
- pynlike of moeilike urinering, onvermoë om die blaas volledig te ledig, edeem;

- pruritus (jeukerigheid), uitslag, urtikarie (swelling, rooiheid en jeukerigheid van die vel), veluitbarsting;
- kortasemigheid;
- gewigstoename, spierpyn, gewrigspyn, aggressiewe of onrustige gedrag;
- hallusinasie, depressie, slapeloosheid, herhalende gedagtes aan of beheptheid met selfdood, nagmerrie;
- hepatitis, abnormale lewerfunksie;
- braking, verhoogde aptyt, naarheid, diaree;
- pruritus (intense gejeuk) wanneer opgehou word om medisyne te gebruik.

Lig asseblief jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegster as jy newe-effekte ervaar. Jy kan ook newe-effekte aanmeld by SAHPRA *via* die Med Safety APP (Medsafety X SAHPRA) en e-verslaggewing platform (who-umc.org) gevind op SAHPRA webwerf. As nadelige reaksies vermoed word kan die ook direk aan die Houer van sertifikaat van registrasie per e-pos of telefonies gerapporteer word:pharmacovigilance.africasme@sunpharma.com of tel:+27(0) 126432000

Deur newe-effekte aan te meld, kan jy help om meer inligting te verskaf oor die veiligheid van CETIZAL 5 TABLETS.

5. Hoe om CETIZAL 5 TABLETS te bewaar

- Bewaar by of benede 25 °C.
- Hou die tablette in die oorspronklike houer tot benodig vir gebruik.
- BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

- Moenie na die vervaldatum soos op die karton of stulpstroke gebruik nie.
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinerings- en rioleringstelsel (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat CETIZAL 5 TABLETS bevat

Die aktiewe bestanddeel in CETIZAL 5 TABLETS is levosetirisiendihidrochloried.

Elke tablet bevat 5 mg levosetirisiendihidrochloried.

Die ander bestanddele is kolloïdale silikadioksied, hipromellose (E464)**,** anhidriese laktose, magnesiumstearaat (E572), mikrokristallyne sellulose (E460a), poliëtileenglikool (E1521), polisorbaat 80 (E433) en titaniumdioksied (E171).

Hoe CETIZAL 5 TABLETS lyk en inhoud van die verpakking

Wit, ovaalvormige, filmbedekte tablette gedruk met ‘S’ op die een kant en ‘n breeklyn op die ander kant. Die keeplyn is slegs om die breek van die tablet te vergemaklik om makliker in te sluk en nie om in gelyke dosisse te verdeel nie.

Wit, ondeursigtige HDPE-bottel met ‘n wit, geriffelde polipropileen kinderbestande skroefprop, induksie-seël en silikagel-droogmiddel.

Verpakking: 30, 90 of 100 tablette.

Wit, ondeursigtige HDPE-bottel met ‘n wit, geriffelde polipropileen skroefprop, induksie-seël en silikagel-droogmiddel.

Verpakking: 100 of 1 000 tablette.

Stulpverpakking

Aluminium PVC stulpverpakking met 10 tablette. 1 stulpstrook (10 tablette) of 3 stulpstroke (30 tablette) word in ‘n karton verpak.

Verpakkingsgrootte: 10 of 30 tablette.

Houer van reistrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

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Roodepoort

Johannesburg

1724

Hierdie inligtingstuk was laas hersien op

07 October 2025

Registrasienommer

44/5.7.1/0017