

Applicant: **Hetero Drugs South Africa (Pty) Ltd**

Product name: **CETORIN 5**

Dosage form: **Film-coated tablets**

Strength: **Levocetirizine dihydrochloride 5 mg /Tablet**

PATIENT INFORMATION LEAFLET FOR CETORIN 5

SCHEDULING STATUS: **S1**

CETORIN 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

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

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

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

CETORIN 5 belongs to a group of medicines called antihistamines. **CETORIN 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).

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

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

Do not take CETORIN 5:

- If you are hypersensitive (allergic) to levocetirizine, similar antihistamines or any of the other ingredients of CETORIN 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 **CETORIN 5** is not recommended for infants and children under 2 years of age.

Warnings and precautions

Take special care with **CETORIN 5**:

- Caution is advised if CETORIN 5 is taken at the same time as alcohol or other agents acting on the brain. In some patients, the concurrent administration of CETORIN 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 **CETORIN 5** is not suitable for children aged 2 – 6 years as no adjusted dosage is possible with **CETORIN 5** which is a film-coated tablet. **CETORIN 5** is therefore not recommended for this age group.

Other medicines and CETORIN 5

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

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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).

CETORIN 5 with food and drink

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

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

Pregnancy and Breastfeeding

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

Do not take **CETORIN 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

CETORIN 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 **CETORIN 5**.

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

CETORIN 5 contains lactose monohydrate

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CETORIN 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 CETORIN 5

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

Always take **CETORIN 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.

CETORIN 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.

Special dosage instructions for specific populations

Elderly patients

No adaptation of the dose is necessary in elderly patients, provided their renal function is normal (see Kidney and liver impairment below).

Kidney and liver impairment

- Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor. Patients who have very severe impairment of kidney function or are on dialysis must not take CETORIN 5.
- Patients who only have impaired liver function should take the usual prescribed dose.
- Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen based on body weight; the dose will be determined by your doctor.

Duration of treatment

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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 CETORIN 5 than you should

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 CETORIN 5

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

4. Possible side effects

CETORIN 5 can have side effects.

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

If any of the following happens, stop taking CETORIN 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 **CETORIN 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,

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- 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.

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,
- 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,

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- 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,
- 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 **CETORIN 5**.

5. How to store CETORIN 5

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package/ container.

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- 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 CETORIN 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.

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

What CETORIN 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.

Pack sizes: 10, 30 film-coated tablets per pack.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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