Austell Pharmaceuticals (Pty) Ltd, Lezlerg 5 mg, Lergilez 5 mg and Levocetirizine 5 mg Austell film-coated tablets

Approved Patient Information Leaflet for Medicines for Human Use:

[PRODUCT NAME]

Please note: This variation application is submitted as a duplicate and hence [PRODUCT NAME] is used in 1.5.5 to indicate the proprietary names as approved and registration numbers as per registration certificates.

Master /Duplicate	Approved proprietary name [PRODUCT NAME]	SAHPRA Registration number
Master	LEZLERG 5 MG	48/5.7.1/1135
Duplicate 1	LERGILEZ 5 MG	48/5.7.1/1134
Duplicate 2	LEVOCETIRIZINE 5 MG AUSTELL	48/5.7.1/1132

SCHEDULING STATUS: S1

[PRODUCT NAME] 5 mg Tablets

Levocetirizine dihydrochloride

Contains sugar: Lactose monohydrate (70,00 mg per tablet)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share [PRODUCT NAME] 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 [PRODUCT NAME] is and what it is used for

2. What you need to know before you take [PRODUCT NAME]

3. How to take [PRODUCT NAME]

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4. Possible side effects

5. How to store [PRODUCT NAME]

6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of [PRODUCT NAME].

[PRODUCT NAME] 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 [PRODUCT NAME]

Do not take [PRODUCT NAME]

- if you are hypersensitive (allergic) to levocetirizine dihydrochloride or any of the other ingredients of [PRODUCT NAME] (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 [PRODUCT NAME]. Take special care with [PRODUCT NAME]:

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 [PRODUCT NAME] may cause seizure aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking [PRODUCT NAME] for several days before testing. This medicine may affect your allergy test results.

Children

The use of [PRODUCT NAME] is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

Other medicines and [PRODUCT NAME]

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

[PRODUCT NAME] with food and, drink and alcohol

Caution is advised if [PRODUCT NAME] is taken at the same time as alcohol or other medicines acting on the brain.

In sensitive patients, the concurrent administration of [PRODUCT NAME] and alcohol or other medicines acting on the brain may cause additional reductions in alertness and impairment of performance.

[PRODUCT NAME] can be taken with or without food.

Pregnancy and, breastfeeding and fertility

You should not take [PRODUCT NAME] 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 [PRODUCT NAME] 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 [PRODUCT NAME] affects them.

Some patients being treated with [PRODUCT NAME] 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.

[PRODUCT NAME] contains lactose monohydrate

[PRODUCT NAME] contain 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 [PRODUCT NAME].

3. How to take [PRODUCT NAME]

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

Always take [PRODUCT NAME] exactly as your doctor or pharmacist has instructed 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.

Method of administration

[PRODUCT NAME] tablets should be swallowed whole with water and may be taken with or without food. You can take [PRODUCT NAME] with meals, or independently of meals. If you have a sensitive stomach, you should best take [PRODUCT NAME] after meals.

If you take more [PRODUCT NAME] 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 [PRODUCT NAME]

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 [PRODUCT NAME]

Stopping treatment with [PRODUCT NAME] earlier than foreseen should have no detrimental effects. However, less frequently pruritus (intense itching) may occur if you stop taking [PRODUCT NAME] 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

[PRODUCT NAME] can have side effects.

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

If any of the following happens, stop taking [PRODUCT NAME] 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 very serious side effects. If you have them, you may have had a serious reaction to [PRODUCT NAME]. 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
- stomach discomfort, 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 "**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 [PRODUCT NAME]**.**

5. How to store [PRODUCT NAME]

- Store all medicines out of reach of children
- Store at or below 25 °C and in the original packaging.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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

Austell Pharmaceuticals (Pty) Ltd, Lezlerg 5 mg, Lergilez 5 mg and Levocetirizine 5 mg Austell film-coated tablets

What [PRODUCT NAME] contains

- The active substance is levocetirizine dihydrochloride.
- The other ingredients are

  Tablet core

  cellulose microcrystalline, colloidal anhydrous silica, lactose monohydrate, and magnesium stearate.

  Film-coating

- hypromellose E464, macrogols – 400 (polyethylene glycol), purified talc, and titanium dioxide E171.

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] tablets are white to off-white, oval, biconvex film-coated tablets with '5' embossed on one side and plain on other side.

[PRODUCT NAME] is supplied in Clear PVDC coated PVC/Aluminium Blisters 4's, 8's, 10's, 20's, 30's, 50's, and 100's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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LEZLERG 5 mg: 48/5.7.1/1135

LERGILEZ 5 mg: 48/5.7.1/1134

LEVOCETIRIZINE 5 mg AUSTELL: 48/5.7.1/1132

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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