SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

GLENCET 5 TABLETS

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **GLENCET 5** with any other person.
- Ask your pharmacist if you need more information or advice
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

1. WHAT GLENCET 5 CONTAINS:

- Each film-coated tablet contains 5 mg levocetirizine dihydrochloride as the active ingredient.
- The other (inactive) ingredients are colloidal silicone dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, opadry white, purified water.

2. WHAT GLENCET 5 IS USED FOR:

GLENCET 5 is used for:

The relief of signs of illness (symptoms) associated with:

- Allergic rhinitis (hay fever) including lasting allergic rhinitis
- Chronic nettle rash of unknown origin

3. BEFORE YOU TAKE GLENCET 5:

Do not take **GLENCET 5:**

- if you are a child younger than 12 years old
- if you are allergic to any of the ingredients contained in **GLENCET 5** (see: "**What GLENCET 5 contains**")
- if you have severe kidney failure
- if you are pregnant (see: "**Pregnancy And Breastfeeding**")
- if you are breastfeeding (see: "**Pregnancy And Breastfeeding**")

Take special care with GLENCET 5

Although GLENCET 5 lacks significant sedative effects there have been reports of drowsiness, tiredness and lack of energy.

Concurrent use of **GLENCET 5** with alcohol is not advised. In sensitive patients, the simultaneous use of **GLENCET 5** and alcohol or other central nervous system depressants may have effects on the nervous system that can lead to additional reduction in awareness and performance of activities.

Taking GLENCET 5 with food and drink:

You may take **GLENCET 5** with or without food or drink.

Pregnancy and breastfeeding:

You should not take **GLENCET 5** if you:

- are pregnant, plan to become pregnant or think you might be pregnant.
- are breastfeeding. **GLENCET 5** can pass through breast milk to the baby.

If you are pregnant or breast feeding your baby while taking **GLENCET 5**, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

Some patients being treated with **GLENCET 5** may experience drowsiness, tiredness and exhaustion. If you are intending to drive, engage in potentially hazardous activities or use machines you are to observe your response to the medication.

Important information about some of the ingredients of GLENCET 5:

GLENCET 5 tablets contain lactose; if you have been told by your doctor that you have intolerance to some sugars such as lactose and galactose you should contact your doctor before taking **GLENCET 5**.

Using other medicines with GLENCET 5:

- Always tell your healthcare professional if you are taking any other medicines. This includes complementary or traditional medicines.,
- Use of Ritonavir (used to treat HIV) increases the concentrations of cetirizine in the blood.
- In sensitive patients the use of Glencet 5 with other central nervous system depressants may have effects on the central nervous system (see "Take special care with Glencet 5").
- Allergy skin tests are inhibited by antihistamine medicine such as GLENCET 5, therefore a wash-out period of 3 days is advised before performing these tests.

4. HOW TO TAKE GLENCET 5:

Always take **GLENCET 5** exactly as instructed. You should check with your doctor or pharmacist if you are unsure.

Adults and children 12 years and older: Take one tablet daily. The tablet

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

Patients with kidney disease should take a lower dose or take the tablets less frequently according to the severity of their kidney disease.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease.

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

If you take more GLENCET 5 than you should:

If you take more **GLENCET 5** than you should, drowsiness can occur in adults. Children may initially show excitation and restlessness followed by drowsiness. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take GLENCET 5:

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

5. POSSIBLE SIDE EFFECTS:

GLENCET 5 may cause side effects.

If any of the following happens stop taking **GLENCET 5** and –tell your doctor immediately or go to the casualty department at your nearest hospital.

- swelling of the hands, feet, ankles, face, lips mouth, or throat, which may cause difficulty in breathing or swallowing
- Rash or itching
- Fainting
- Yellowing of skin and eyes, also called jaundice

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

Frequent side effects includes dry mouth, headache, tiredness, weight increase, pharyngitis (sore throat and discomfort when swallowing), naso-pharyngitis, dyspnoea (shortness of breath) and somnolence/drowsiness have been reported.

Less frequent- side effects includes nausea, exhaustion, aching muscles, abdominal discomfortand allergic reactions Other side effects such as fast or irregular heartbeats, convulsions, visual disturbances, oedema (water retention), pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), aggressive or agitated behaviour, hallucination, depression, hepatitis, and abnormal liver function have also been reported.

Not all side effects reported for this medicine are included in this leaflet.

Should your general health worsen while taking **GLENCET 5**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

6. STORAGE AND DISPOSING OF GLENCET 5:

Store all medicines out of reach of children.

- Keep the medicine in its original container.
- Store the medicine at or below 25 °C and protect from moisture.
- Do not use after the expiry date stated on the blister or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION OF GLENCET 5:

GLENCET 5 tablets are packed in blisters packs and are available in pack sizes of 7's, 10's and 30's. 7's is packed in Alu/Hard tempered aluminium foil blister packs 10's and 30's are packed in White opaque, PVC/PVDC/Aluminium foil blister packs.

The blister strips are packed into cardboard boxes.

8. IDENTIFICATION OF GLENCET 5:

White oval film coated biconvex tablet, one side embossed with G break line G (G on both sides of the break line) and the other side plain.

9. REGISTRATION NUMBER:

A 44/5.7.1/0843

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Activo Health (Pty) Ltd

Block B, Arena Office Park

272 West Avenue, Centurion

0157

11. DATE OF PUBLICATION:

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