PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

CETICIT 10 mg (film-coated tablet)

Cetirizine dihydrochloride

Contains sugar: Lactose monohydrate

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

CETICIT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **CETICIT** carefully to get the best results from it.

- Keep this leaflet. You may need it to read it again.
- Do not share **CETICIT** 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.

What is in this leaflet

1. What CETICIT is and what it is used for

CETICIT (cetirizine dihydrochloride 10mg).

The active substance cetirizine dihydrochloride, is part of a group of molecules with antihistaminic activity.

CETICIT is used for symptomatic relief of allergic conditions such as allergic rhinitis (hay fever), and allergic skin conditions, associated with pruritus (severe itching), such as urticarial (hives or itchy areas of the skin).

2. What you need to know before you take CETICIT

Do not take CETICIT

- If you are hypersensitive (allergic) to cetirizine dihydrochloride or hydroxyzine, any piperazine derivatives, or any of the other ingredients of **CETICIT.**
- If you are pregnant, as the safety of this medicine in pregnant women has not been determined.
- If you are breastfeeding, since cetirizine dihydrochloride passes into the breast milk.
- If the child you are caring for is under the age of 2 years, as it is not yet known whether this medicine is safe or effective in this age group.
- If you suffer from severe renal impairment (kidney disease).
- If you suffer from asthma, as it may cause obstruction of the airways (tight chest) if you have previously experienced adverse reactions to this type of medicine.

Warnings and precautions

Take special care with CETICIT

- If you are going to perform hazardous activities or if you are driving or operating machinery; as your mental alertness and physical coordination may be impaired.
- If you are taking alcohol, as this may lead to drowsiness when taken with **CETICIT**.
- If you suffer from conditions that may increase the risk of urinary retention (unable to empty your bladder), e.g., spinal cord lesion, prostatic hyperplasia (prostate gland enlargement).
- If you suffer from epilepsy and or convulsions (spasms / seizures).
- if you are advised by your doctor to have an allergy skin test done, as **CETICIT** interferes with the outcome of the test results. You should stop taking **CETICIT** 3 days prior to a scheduled allergy skin test.
- When you stop taking **CETICIT,** pruritus (severe itching) and/or urticaria (itchy, raised red areas on the skin) may occur when **CETICIT** is stopped, even if those symptoms were not present before you started taking **CETICIT**. The symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.
- If you suffer from the rare hereditary (inherited) condition of galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance as **CETICIT** contains lactose.
- If you suffer from diabetes mellitus, as lactose may have an effect on your sugar control.
- If you suffer from porphyria (a metabolic disease of blood components, affecting the skin and nervous system).

Children and adolescents

Do not give CETICIT to children under the age of two years, as safety and efficacy have not been demonstrated.

Do not give CETICIT to children under the age of six years, as the tablet do not allow for an appropriate dose for this age group.

Other medicines and CETICIT

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

- There are no known interactions with other medicines, including pseudoephedrine (a medicine used to treat a blocked nose) or theophylline (used to treat a tight chest).
- Diazepam (a calming medicine), glipizide (to treat diabetes), pseudoephedrine (a medicine used to treat a blocked nose), ketoconazole (to treat fungal and yeast infections), azithromycin and erythromycin (to treat bacterial infections) and cimetidine (to treat acid reflux) have not shown evidence of interactions with **CETICIT**.
- As with other antihistamines it is advisable to avoid excessive alcohol consumption and other sedating medicines .

CETICIT with food and alcohol

The amount of cetirizine taken up by your body is not affected by food, but it may happen at a slower rate.

Since alcohol may compound the drowsiness and impaired concentration that may be caused by **CETICIT,** alcohol should not be taken simultaneously with **CETICIT**.

Pregnancy and breastfeeding

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.

CETICIT is contraindicated in pregnancy as the safety has not been established.

CETICIT is contraindicated in lactating women since the active ingredient is excreted in breast milk.

Driving and using machines

- **CETICIT** may make you feel drowsy.
- **CETICIT** could interfere with your ability to drive safely.
- Do no operate any tools or machines when using **CETICIT.**

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

CETICIT contains lactose. Patients with the rare hereditary (inherited) conditions of galactose intolerance e.g., galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **CETICIT**.

Lactose may have an effect on the glycaemic control of patients with diabetes mellitus**.**

3. How to take CETICIT

The usual dose is as follows:

Adults or children 12 years of age or older:

One 10 mg tablet daily once daily.

Children 6 to 12 years old:

10 mg (one tablet) once daily or 5 mg (half a tablet) twice daily.

Dosage in patients with kidney impairment (deficiency / disease)

In patients with kidney disease, half the recommended daily dose of cetirizine should be taken.

Dosage in liver impairment (deficiency / disease)

In patients with liver disease, half the recommended daily dose should be taken.

Dosage in the elderly

No dose adjustment is necessary.

If you use more CETICIT than you should

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

Drowsiness (sleepiness) may be expected with an overdosage of **CETICIT.** Overdosage may produce agitation, confusion, diarrhoea, dizziness, headache, mydriasis (dilation of the pupil), restlessness, somnolence (a state of drowsiness), stupor (a state of near-unconsciousness), pruritus (severe itching) sleepiness, itching, skin rash, difficulty in urinating, exhaustion, tremor and an increased heart rate.

If you forget to take CETICIT

Do not take a double dose to make up for forgotten individual doses. Take **CETICIT** as soon as possible after the forgotten dose and then continue with the normal dose.

If you stop taking CETICIT

When you stop taking **CETICIT**, pruritus (severe itching) and/or urticaria (itchy, raised red areas on the skin) may occur even if these symptoms were not present before starting treatment with **CETICIT**. The symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

4. Possible side effects

CETICIT can have side effects.

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

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other health care professional for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in breathing;
- rash or itching;
- fainting.

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

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

- you pass less urine than normal;

- a tight chest or difficulty in breathing;
- increase in epileptic seizures (if you are an epileptic patient);
- abdominal pain, muscle weakness, -cramping or -pain, darkening of the skin, skin rashes, skin blisters, increased heart rate, confusion which may be symptoms of porphyria problems (if you are a porphyria patient).

These all are serious side effects. You may need urgent medical attention. **CETICIT.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pharyngitis (sore throat), rhinitis (a congested, itchy, and runny nose).

Less frequent side effects:

- Urticaria (itchy, raised red areas on the skin), skin rash, pruritus (severe itching), angioedema (an allergic skin disease characterised by swelling of the surrounding skin and the mucous membranes).
- Somnolence (a state of drowsiness), depression, confusion, agitation, aggression, hallucinations (visions and imaginations), insomnia (suffering to fall asleep).
- Drowsiness, fatigue, malaise (general feeling of discomfort, illness, or lack of well-being), asthenia (weakness; lack of energy and strength), tics.
- Blurred vision, oculogyration (uncontrolled and repetitive movement of the eye).
- Tinnitus (ringing sound in ear), vertigo (feeling off-balance)
- Palpitations (a rapid and irregular heartbeat), dysrhythmias (abnormal heartbeat), tachycardia (increased heart rate).
- Hypotension (low blood pressure).
- Thickening of mucous, bronchospasm (tight chest / shortness of breath)

- Nausea, gastrointestinal (stomach) discomfort, diarrhoea (runny stomach), constipation, dry mouth.
- Jaundice (a condition in which the skin and whites of the eyes become yellow).
- Fixed drug-eruption (hyperpigmentation of the skin), photosensitivity (increased sensitivity of the skin to light), hair loss, sweating.
- Myalgia (muscle aches and pains).
- Dysuria (discomfort or burning with urination), enuresis (bed-wetting), urinary retention (unable to emptying your bladder).
- Oedema (build-up of fluid in the body which causes the affected tissue to become swollen).
- Weight increase.

Frequency unknown side effects:

- Increased appetite.
- Suicidal ideation (thinking about suicide), nightmares.
- Headaches, dizziness, anxiety, nervousness, paraesthesia (tingling or pins-and-needles), convulsions (spasms / seizures), movement disorders, dysgeusia (a distortion of the sense of taste), syncope (temporary loss of consciousness), tremor, dystonia (a state abnormal of muscle tone), dyskinesia (writhing movements of the face), amnesia (forgetfulness), memory loss.
- Hepatitis (inflammation in the liver).
- Acute generalised exanthematous pustulosis (a skin reaction related to medication).
- Arthralgia (pain in a joint).

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 or other health care provider. 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 **CETICIT.**

Adverse Drug Reactions may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com.

5. How to store CETICIT

Store at or below 25 °C.

Keep tablets in dry place. Protect from light.

Do not remove the blisters from the carton until required for use.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What CETICIT contains

The active substance is cetirizine dihydrochloride. Each tablet contains 10 mg.

The other ingredients are:

calcium hydrogen phosphate anhydrous,

colloidal anhydrous silica,

hypromellose (E-5),

maize starch,

magnesium stearate,

povidone (K-30),

propylene glycol,

purified talc,

sodium starch glycolate (type-A),

titanium dioxide and lactose monohydrate,

lactose monohydrate (sugar).

What CETICIT looks like and contents of the pack

Film coated tablets

White, capsule shaped, film-coated tablets with break line on one side and "M+" embossed on the other side.

Packaged in blisters strips of 10's. Available in cartons of 10’s, 20’s or 30’s.

Not all pack sizes may be marketed at the same time.

Holder of certificate of registration

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