Clean Patient Information Leaflet for Medicines for Human Use:

CETIRIZINE 5 mg AUSTELL

CETIRIZINE 10 mg AUSTELL

SCHEDULING STATUS: S1

CETIRIZINE 5 mg AUSTELL film-coated tablets

CETIRIZINE 10 mg AUSTELL film-coated tablets

Cetirizine dihydrochloride

Contains sugar: lactose monohydrate

CETIRIZINE 5 mg AUSTELL film-coated tablets:

Each film coated tablet contains 68,00 mg lactose monohydrate.

CETIRIZINE 10 mg AUSTELL film-coated tablets:

Each film coated tablet contains 65,00 mg lactose monohydrate.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CETIRIZINE AUSTELL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What CETIRIZINE AUSTELL is and what it is used for

2. What you need to know before you take CETIRIZINE AUSTELL

3. How to take CETIRIZINE AUSTELL

4. Possible side effects

5. How to store CETIRIZINE AUSTELL

6. Contents of the pack and other information

1. What CETIRIZINE AUSTELL is and what it is used for

CETIRIZINE AUSTELL contains the active substance called cetirizine dihydrochloride which belongs to the group of medicines called antihistamines.

CETIRIZINE AUSTELL is used for the relief of allergic conditions such as allergic rhinitis (hayfever), rhinitis (runny nose) and allergic skin conditions such as urticaria (swelling, redness and itchiness of the skin).

2. What you need to know before you take CETIRIZINE AUSTELL

Do not take CETIRIZINE AUSTELL:

- if you are hypersensitive (allergic) to cetirizine dihydrochloride, or to hydroxyzine or any of the ingredients of CETIRIZINE AUSTELL (listed in section 6).
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).
- if you have severe kidney problems.
- if you have asthma and you have previously experienced side effects to antihistamines.
- Children under the age of two years should not take CETIRIZINE AUSTELL, as safety and efficacy have not been demonstrated.

Warnings and precautions

Take special care with CETIRIZINE AUSTELL:

- This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.
- if you are a patient with kidney problems, please ask your health care provider for

advice; if necessary, you will take a lower dose.

- if you have difficulty passing urine (like spinal cord problems or prostate or bladder problems), you should ask your health care provider for advice.

- if you experience symptoms such as a sudden onset of fever, reddening of the skin with blisters containing pus, stop giving this medicine immediately and talk to a doctor or pharmacist (see section 4).
- if you are an epileptic or at risk of convulsions (fits), as you must be closely monitored.
- if you are scheduled for allergy testing, you must stop taking CETIRIZINE AUSTELL at least 3 days before testing, as CETIRIZINE AUSTELL may affect your allergy test results.
- if you have porphyria, as this medicine should be used with caution in such patients.

Children and adolescents

Children under the age of two years should not be given CETIRIZINE AUSTELL as safety and efficacy have not been established.

Other medicines and CETIRIZINE AUSTELL

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

- Avoid taking alcohol or any other medicines that may make you drowsy (sedatives, tranquilisers or strong painkillers) with AUSTELL CETIRIZINE.

CETIRIZINE AUSTELL with food and alcohol

- As with other antihistamines it is advisable to avoid excessive alcohol consumption.
- You can take CETIRIZINE AUSTELL with or without food. Food may make it take a little longer to start working, but it will not reduce the overall effect.

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 CETIRIZINE AUSTELL.

Safety in pregnancy and lactation has not been established.

The active ingredient, cetirizine is excreted in milk, and therefore CETIRIZINE AUSTELL, should be

avoided during breastfeeding.

Driving and using machines

It is not always possible to predict to what extent CETIRIZINE AUSTELL 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 CETIRIZINE AUSTELL affects them. CETIRIZINE AUSTELL lacks significant sedative effects. Patients should be warned, however, that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants (see CETIRIZINE AUSTELL with food and alcohol).

The patient's ability to perform hazardous activities requiring mental alertness or physical coordination such as driving or operating machinery may be impaired.

CETIRIZINE AUSTELL contains lactose monohydrate

If you have been told that you have an intolerance to some sugars, contact your doctor before taking CETIRIZINE AUSTELL.

3. How to take CETIRIZINE AUSTELL

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

Always take CETIRIZINE AUSTELL exactly as described in this leaflet or as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose for CETIRIZINE AUSTELL is:

Adults or children 12 years of age or older:

Take one 10 mg tablet orally once daily.

Children 6 to 12 years old:

Take one 10 mg tablet orally once daily or 5 mg orally twice daily.

Dosage in elderly:

No dose adjustment is necessary in healthy elderly patients with normal renal function.

Dosage in renal impairment:

In patients with renal impairment, where the creatinine clearance is less than 40 mL/min, the recommended daily dose of cetirizine should be halved.

Dosage in hepatic impairment:

In moderate to severe hepatic impairment half the recommended daily dose should be used.

If you take more CETIRIZINE AUSTELL than you should:

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

Drowsiness is an expected symptom of overdosage. Overdosage in children may product agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor and tachycardia. There is no specific antidote. Cetirizine is not effectively removed by dialysis. Further

treatment is symptomatic and supportive.

If you forget to take CETIRIZINE AUSTELL

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

4. Possible side effects

CETIRIZINE AUSTELL can have side effects.

Not all side effects reported for CETIRIZINE AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CETIRIZINE AUSTELL, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking CETIRIZINE AUSTELL 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 CETIRIZINE AUSTELL. 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:

- recurring thoughts of harming or killing yourself

- convulsions (fits)
- rapid heartbeat
- abnormal liver function tests
- sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalised Exanthematous Pustulosis – AGEP) may occur within the first 2 days of treatment with this medicine.

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:

- runny nose
- sleepiness
- sore throat
- headache, dizziness, fatigue
- dryness of the mouth, nausea
- anxiety.

Less frequent side effects:

- blood disorders such as decrease in blood platelets which causes bleeding or bruising
- agitation, aggression, depression, confusion, insomnia, hallucinations
- repeated and involuntary twitches, movements, or sounds (tics)
- tingling in the hands and feet, tremor
- dysgeusia (altered taste), dystonia (abnormal prolonged muscular contractions), dyskinesia (involuntary movements)
- accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements), blurred vision

- diarrhoea
- swelling, redness and itching of the skin
- angioedema
- pain or a burning sensation when you urinate or involuntary urination
- asthenia (weakness or lack of strength)
- malaise (a general feeling of being unwell)
- increased weight.

Side effects with frequency unknown:

- increased appetite
- drowsiness, nervousness
- amnesia, memory impairment
- eye pain
- vertigo
- thickening of mucous
- upset stomach
- hepatitis
- joint pain
- inability to pass urine
- trouble getting or keeping an erection
- pruritus (intense itching) when you stop giving this medicine.

If you notice any side effects not listed in this leaflet, please ~~tell~~ 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform

(who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CETIRIZINE AUSTELL.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store CETIRIZINE AUSTELL

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Protect from light
- Keep the blister packs in the outer carton until required for use
- Store in the original container
- Keep the securipack tightly closed.
- 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 and sewerage systems (e.g toilets).

6. Contents of the pack and other information

What CETIRIZINE AUSTELL contains

- The active substance is cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate, maize starch, pregelatinised starch, dried maize starch, purified talc and magnesium stearate.
- The film-coating consists of hydroxypropyl methylcellulose (hypromellose), macrogol 6000, titanium dioxide and purified talc.

CETIRIZINE 5 mg AUSTELL film-coated tablets:

Each film coated tablet contains cetirizine dihydrochloride 5 mg.

CETIRIZINE 10 mg AUSTELL film-coated tablets:

Each film coated tablet contains cetirizine dihydrochloride 10 mg.

What CETIRIZINE AUSTELL looks like and contents of the pack

CETIRIZINE 5 mg AUSTELL**:**

White to creamish white capsule shaped film coated tablets with breakline and ‘B’ & ‘L’ embossed on either side of the breakline and ‘5’ embossing on the other side.

CETIRIZINE 10 mg AUSTELL:

White to creamish white capsule shaped film coated tablets with scoreline and ‘B’ & ‘L’ debossed on either side of the scoreline and ‘10’ debossing on the other side.

CETIRIZINE 5 mg AUSTELL are supplied in:

- Blister packs (Clear PVC/Aluminium foil) of 1 x 10, 3 x 10 and 10 x 10 tablets. Pack sizes of 10, 30 or 100 film-coated tablets.
- Bulk packs (White HDPE Jars) of 250, 500 and 1 000 film-coated tablets.

CETIRIZINE 10 mg AUSTELL are supplied in:

- Blister packs (Clear PVC/Aluminium foil) of 1 x 10, 3 x 10 and 10 x 10 tablets. Pack sizes of 10, 30 or 100 film-coated tablets.
- Bulk packs (White HDPE Jars) of 250, 500 and 1 000 film-coated tablets.

Austell Pharmaceuticals (Pty) Ltd, 370579-80, Cetirizine 5 mg / 10 mg Austell, film-coated tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration numbers

CETIRIZINE 5 mg AUSTELL film-coated tablets: 37/5.7.1/0579

CETIRIZINE 10 mg AUSTELL film-coated tablets: 37/5.7.1/0580

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

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