

CLEAN PROPOSED PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:**

S2

CETIRIZINE 10 GULF (tablets)**Cetirizine****Contains sugar (84 mg lactose/tablet)**

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

Cetirizine 10 Gulf is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **Cetirizine 10 Gulf** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Cetirizine 10 GULF** 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 7 days.

What is in this leaflet

1. What **CETIRIZINE 10 GULF** is and what it is used for
2. What you need to know before you take **CETIRIZINE 10 GULF**
3. How to take **CETIRIZINE 10 GULF**
4. Possible side effects
5. How to store **CETIRIZINE 10 GULF**
6. Contents of the pack and other information

1. What Cetirizine 10 Gulf is and what it is used for

Indicated for the symptomatic relief of the symptoms of allergic rhinitis (more commonly referred to as hay fever, which is an inflammation of the nasal passages caused by allergic reaction to airborne substances) and urticaria (redness of the skin often accompanied by itching).

2. What you need to know before taking Cetirizine 10 Gulf

Do not use Cetirizine 10 Gulf if:

- you are sensitive or ever had a harmful reaction to cetirizine or any of the inactive ingredients in **Cetirizine 10 Gulf**, hydroxyzine or other antihistamines
- you are breast feeding since the active ingredient is excreted in breast milk
- you are pregnant as the safety in pregnancy has not been established
- in children under 2 years of age

Warnings and precautions

Take special care with **Cetirizine 10 Gulf**

- in the elderly
- in patients with hepatic or renal impairment
- if you operate or drive machinery as mental alertness or physical co-ordination may be impaired (see below "Driving and using machinery")
- if you are lactose intolerant

Other medicines and Cetirizine 10 Gulf

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

It is especially important if you have taken any alcoholic drinks or any medicine that may cause drowsiness.

Cetirizine 10 Gulf with food and drink

Cetirizine 10 Gulf can be taken before or after meals. Avoid any alcoholic drink while you are taking **Cetirizine 10 Gulf**.

Pregnancy or breastfeeding

Safety in pregnancy and breastfeeding has not been established.

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 professional for advice before taking this medicine

Driving and using machines

Cetirizine 10 Gulf may lead to drowsiness and impaired concentration which may be aggravated by simultaneous intake of alcohol or other central nervous system depressants (E.g. sedatives and tranquilisers). Caution should be used when driving or operating machinery or performing dangerous tasks, where loss of concentration may lead to accidents.

If you are affected do not drive or use machines.

Cetirizine 10 Gulf contains lactose

If you have been told that you have an intolerance to some sugars, contact your doctor before taking **Cetirizine 10 Gulf**

3. How to take Cetirizine 10 Gulf

Do not share medicines intended for you with others.

Always take **Cetirizine 10 Gulf** 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.

Take the tablet with a glass of water. Do not take more than one tablet each day.

Adults or children 12 years of age or older: Take one tablet (10 mg) daily

Children aged 6 to 12 years old: Take one tablet (10 mg) daily or half a tablet (5 mg) twice a day.

Cetirizine 10 Gulf is not suitable for children under 6 years.

If you take more Cetirizine 10 Gulf than you should

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

Drowsiness is an expected symptom of overdosage. Overdosage in children may produce agitation, somnolence (drowsiness), pruritus (severe itching), rash, urinary retention, fatigue, tremor and tachycardia (fast heartbeat).

If you forget to take Cetirizine 10 Gulf

If you forget a dose, take the next one as soon as you remember unless it is time or almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Cetirizine 10 Gulf can have side effects.

Not all side effects reported for **Cetirizine 10 Gulf** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Cetirizine 10 Gulf**, please consult your health care provider for advice.

You must stop taking **Cetirizine 10 Gulf** and speak to your doctor straight away if you notice the following symptoms:

A severe allergic reaction including rash, itchiness and fever. This reaction may start soon after you first take **Cetirizine 10 Gulf**, or it might start later

These are all very serious side effects. If you have them, you may have had a serious reaction to **Cetirizine 10 Gulf**. 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:

- fast heartbeat

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:

- tiredness, feeling sleepy
- pain in the abdomen
- dry mouth
- nausea
- diarrhoea or constipation
- thickening of mucous
- Increased or loss of appetite
- tinnitus (ringing in the ears)
- blurred vision

Less frequent side effects:

- itching and rash, urticaria (hives)
- feeling agitated, feeling weak or generally unwell
- drowsiness
- sleeplessness
- increased sweating
- sensitivity to light
- urinary retention
- Headache
- Dizziness

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 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 **CETIRIZINE 10 GULF**.

5. How to store CETIRIZINE 10 GULF

Store at or below 25 °C. Protect from excessive moisture and store in a dry place.

Do not remove tablets from blisters until required for use. Keep containers tightly closed. Keep all medicines in a safe place, out of reach of children.

Do not use **Cetirizine 10 Gulf** beyond the date indicated on the container.

Return all unused or expired medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Cetirizine 10 Gulf contains:

The active substance is cetirizine

Each film coated tablet contains 10 mg cetirizine dihydrochloride

The other ingredients are:

Lactose, starch, polyvinyl pyrrolidone, magnesium stearate

What Cetirizine 10 Gulf looks like and contents of the pack

White oblong film coated tablet, with a central break line on both sides

- Tablets are packed into clear PVC/ silver Al blister strips containing 10 tablets each; packed into unit carton as 10 (1 blister), 30 (3 blisters) or 250 (25 blisters) tablets.
- White HDPE containers of 28, 30, 100 tablets
- 28 tablets packed in patient ready packs.

Holder of Certificate of Registration

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This leaflet was last revised in

07-02-2023

Registration number:

41/5.7.1/0555