PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

Cetirizine 10 Unicorn 10 mg film-coated tablets

Cetirizine dihydrochloride

Contains sugar (as lactose 63, 5 mg per film-coated tablet)

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

- Keep this leaflet. You may need to read it again.
- Do not share Cetirizine 10 Unicorn 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 a few days.

What is in this leaflet

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

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

Cetirizine 10 Unicorn belongs to the antihistamine group of medicines.

Cetirizine 10 Unicorn treats adults and children aged 6 years and over suffering from

- hay fever or allergic rhinitis (causes itchy or watery eyes, sneezing and a runny nose), as a result of allergies to pollen, dust or pets and
- urticaria (swelling, redness and itchiness of the skin).

2. What you need to know before you take Cetirizine 10 Unicorn

Do not take Cetirizine 10 Unicorn

- if you have a history of hypersensitivity or are hypersensitive (allergic) to cetirizine dihydrochloride, hydroxyzine, piperazine medicines or any of the other ingredients of Cetirizine 10 Unicorn (listed in section 6).
- if you have severe kidney problems
- if you are pregnant or breastfeeding
- if your child is less than 2 years of age.
- If you are not sure whether you should be taking Cetirizine 10 Unicorn, please discuss with your doctor before taking Cetirizine 10 Unicorn.

Warnings and precautions

Special care should be taken with Cetirizine 10 Unicorn:

- If you have a history of epilepsy (seizure/fits/convulsions),
  talk to your doctor before taking this medicine.
- You should avoid alcohol consumption whilst taking Cetirizine 10 Unicorn
- Talk to your doctor or pharmacist before taking these tablets if you have kidney problems as you may need to take a lower dose.
- If you are having an allergy skin test you need to wait 3 days after taking Cetirizine 10 Unicorn.
- If you have an enlarged prostate or any other conditions that causes difficulty in emptying your bladder. Cetirizine 10 Unicorn. may increase the risk of having difficulty in passing water.

Children and adolescents

Cetirizine 10 Unicorn are not suitable for children younger than 6 years as it is difficult to get the correct dose when using a tablet.

Other medicines and Cetirizine 10 Unicorn

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

Cetirizine 10 Unicorn with food, drink and alcohol

Be careful when drinking alcohol while using Cetirizine 10 Unicorn, as your level of alertness may be reduced.

Pregnancy and, breastfeeding and fertility

You should not take Cetirizine 10 unicorn if you are pregnant or 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.

Driving and using machines

Cetirizine 10 Unicorn may cause drowsiness. If you feel drowsy or dizzy you should not drive or operate machines.

It is not always possible to predict to what extent Cetirizine 10 Unicorn may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which Cetirizine 10 Unicorn affects you.

Cetirizine 10 Unicorn contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars e.g. lactose do not take Cetirizine 10 Unicorn.

3. How to take Cetirizine 10 Unicorn

Do not share medicines prescribed for you with any other person

Always take Cetirizine 10 Unicorn exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor or pharmacist if you are not sure. Your doctor may reduce the dose if you have kidney or liver problems.

The usual dose is:

Adults or children 12 years and older: one 10 mg tablet once daily.

Children 6 to 12 years of age: one 10 mg tablet once a day, or 5 mg (half a tablet) two times a day. To divide the tablet, place it on a firm surface with the score line facing up, and gently apply pressure with the thumb.

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If you have kidney problems you should talk to your doctor or pharmacist for advice before taking these tablets as a lower dose may be required.

- Do not take more than the recommended dose.
- Do not give to children under 6 years.

If you have the impression that the effect of Cetirizine 10 Unicorn is too strong or too weak, tell your doctor or pharmacist.

If you take more Cetirizine 10 Unicorn than you should

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

Possible signs of an overdose: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence tachycardia, tremor and urinary retention.

If you forget to take Cetirizine 10 Unicorn

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

If you stop taking Cetirizine 10 Unicorn

Rarely, pruritus (intense itching) and/or urticaria may occur. If your symptoms persist, see your doctor.

If you have any further questions on the use of this medicine, ask your doctors or pharmacist.

4. Possible side effects

Cetirizine 10 Unicorn can have side effects.

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

If any of the following happens, stop taking Cetirizine 10 Unicorn and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of an allergic reaction such as developing a rash, swelling of the mouth or face or difficulty breathing

- Bruising or bleeding more easily than normal
- Convulsions or fits
- Loss of consciousness.

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

- Confusion, hallucinations,
- Rapid heartbeat,
- yellowing of eyes and skin, fatigue, vomiting, stomach pain (may indicate a liver problem).

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:

- headache or dizziness
- drowsiness or tiredness
- dry mouth
- sore throat
- nausea (feeling sick).

Less frequent side effects:

- agitation
- heart palpitations
- irregular heartbeat
- weakness
- feeling unwell
- pins and needles
- itching

- rash or hives
- aggression
- depression
- weight gain
- abdominal pain
- diarrhoea
- swelling
- insomnia
- movement disorders including tremor
- muscle spasm
- tics
- taste disorder
- blurred vision
- eye movement disorder
- difficult or painful or involuntary urination

Frequency Unknown:

- increased appetite
- skin eruptions
- joint pain
- memory loss
- difficulty passing urine or a feeling of dizziness.
- in very rare cases people have had suicidal thoughts when taking this medicine.

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. 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. By reporting side effects, you can help provide more

information on the safety of Cetirizine 10 Unicorn.

5. How to store Cetirizine 10 Unicorn

Store all medicines out of reach of children.

Do not use this medicine after the 'EXPIRY' date shown on the pack.

- Store at or below 25 °C
- Keep tablets in a dry place.
- 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

What Cetirizine 10 Unicorn contains

- The active substance: Each film coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are:

  Dry mixing: Cellulose microcrystalline, colloidal anhydrous silica, croscarmellose sodium, Lactose, magnesium stearate.

  Film coating: Tabcoat TC film coating product TC – 580034 white (Hypromellose, polydextrose, titanium dioxide, polyethylene Glycol/macrogol), purified water.

What Cetirizine 10 Unicorn looks like and contents of the pack

White to off white, film coated capsule shaped tablet, with score on one face of the tablet.

Cetirizine dihydrochloride 10 mg tablets are packages in clear transparent PVC/PVDC foil blister packs.

Each blister contains 15 tablets, which are placed in an outer carton containing 30 tablets.

Holder of Certificate of Registration

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