

Approved Patient Information Leaflet for Medicines for Human Use:

ZELARY 10

SCHEDULING STATUS: S1

ZELARY 10 mg film-coated tablet

Cetirizine dihydrochloride

Contains sugar: lactose monohydrate

Each film-coated tablet contains 105 mg lactose monohydrate.

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

ZELARY 10 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ZELARY 10 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ZELARY 10 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 ZELARY 10 is and what it is used for
2. What you need to know before you take ZELARY 10
3. How to take ZELARY 10
4. Possible side effects
5. How to store ZELARY 10
6. Contents of the pack and other information

1. What ZELARY 10 is and what it is used for

ZELARY 10 contains the active substance called cetirizine dihydrochloride which is a non-sedating antihistamine.

ZELARY 10 is used:

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- In adults and children aged 6 years and above, ZELARY 10 can rapidly relieve allergy symptoms such as sneezing, runny nose and itchy, burning eyes, whether these are due to hay fever or whether they occur all year round.
- ZELARY 10 may also be taken for allergic skin conditions such as rash, itching or urticaria (hives).

2. What you need to know before you take ZELARY 10

Do not take ZELARY 10

- if you are hypersensitive (allergic) to cetirizine, hydroxyzine, any piperazine derivatives or any of the other ingredients of ZELARY 10 (listed in section 6).
- if you are pregnant or think that you are pregnant or if you are breast-feeding.
- if you have an end-stage kidney disease (severe renal failure requiring dialysis)
- if you suffer from asthma and have previously experienced side effects to antihistamines
- in children under 2 years of age

Warnings and precautions

Some patients may experience sedative effects such as drowsiness or sleepiness. It is recommended to avoid the simultaneous use of alcohol with cetirizine as this may add to these effects as well as influence alertness and ability to drive and use machines.

Take special care with ZELARY 10 and speak to your doctor:

- if you have porphyria
- If you have problems passing urine (like spinal cord problems or prostate or bladder problems)
- if you are an epileptic patient (have fits) or a patient at risk of convulsions
- if you are scheduled for allergy testing, you should stop taking ZELARY 10 at least 3 days before testing, since it may affect your allergy test results.
- It is recommended to avoid taking cetirizine with alcohol.

Children

Do not give ZELARY 10 to children below the age of 6 years because the tablet formulation does not

allow the necessary dose adjustments.

Other medicines and ZELARY 10

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

There have been no reports of undesirable effects occurring when ZELARY 10 tablets has been taken at the same time as other medicines.

ZELARY 10 with food and alcohol

ZELARY 10 can be taken before or after meals.

Avoid drinking alcohol whilst taking ZELARY 10 tablets.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast feeding, 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 ZELARY 10.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

It is not always possible to predict to what extent ZELARY 10 may interfere with the daily activities of a patient. It is advisable to determine individual response before driving or performing complicated tasks, where loss of concentration may lead to accidents. ZELARY 10 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).

ZELARY 10 contains lactose

This medicine contains lactose monohydrate. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ZELARY 10

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

Always take ZELARY 10 exactly as described in this leaflet or as your doctor or pharmacist have told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose of ZELARY 10 tablets for adults and children aged 12 years and over is: one tablet (10 mg) to be swallowed once daily.

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

ZELARY 10 is not suitable for children under 6 years.

Half the recommended daily dose of cetirizine (5 mg) should be taken in patients with renal or liver impairment.

Method of administration

ZELARY 10 is for oral use only.

If you take more ZELARY 10 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 produce agitation, somnolence (drowsiness), pruritus (severe itching), rash, urinary retention, fatigue, tremor and tachycardia (fast heartbeat).

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, malaise (feeling unwell), ailing, dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in completely emptying the bladder) have been reported.

If you forget to take ZELARY 10

If you forget to take it, take your recommended dose 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

ZELARY 10 can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general state of health worsens or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.

If any of the following happens, stop taking ZELARY 10 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 ZELARY 10. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- somnolence (sleepiness)
- headache, dizziness
- fatigue
- pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children)
- nausea, dry mouth, gastrointestinal discomfort

Less frequent side effects:

- thrombocytopenia (low levels of blood platelets)
- allergic reactions, some severe (very rare)
- agitation
- depression, hallucination, aggression, confusion, insomnia
- Tics (habit spasm)
- suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- paresthesia (abnormal feelings of the skin)
- convulsions
- syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- drowsiness, anxiety, nervousness
- blurred vision, accommodation disorder (difficulty focusing), oculogyric crisis (eyes having uncontrolled circular movements)
- thickening of mucous
- increased appetite
- diarrhoea
- liver function abnormal
- pruritus (intense itching) and/or urticaria (hives) upon discontinuation)
- angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption (drug allergy)
- abnormal elimination of urine (bed wetting, pain and/or or difficulty passing water).
- asthenia (extreme fatigue), malaise (feeling unwell)
- oedema (swelling)
- weight increased.

Side effects with frequency unknown:

- increased appetite

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- amnesia (memory loss) memory impairment
- vertigo (sensation of rotation or movement)
- hepatitis (inflammation of the liver)
- acute generalized exanthematous pustulosis (rash with blisters containing pus)
- arthralgia (joint pain), myalgia (muscular pain)
- urinary retention (inability to completely empty the urinary bladder).

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 or 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 ZELARY 10.

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 ZELARY 10

Store at or below 25 °C. Protect from light.

Keep blisters in carton until required for use.

Do not use after the date which is stamped on the pack.

Do not share medicines prescribed for you with others.

Store all medicines out of reach of children.

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

6. Contents of the pack and other information

What ZELARY 10 contains

Austell Pharmaceuticals (Pty) Ltd, 37/5.7.1/0428, ZELARY 10, film-coated tablets, 10 mg

- The active substance is cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate, maize starch, povidone, magnesium stearate, hypromellose, propylene glycol, titanium dioxide and talc.

Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

Contains sugar: lactose monohydrate 105 mg.

What ZELARY 10 looks like and contents of the pack

White, circular biconvex film-coated tablets with a score line on one side.

The tablet can be divided into equal halves.

ZELARY 10 tablets are packed in clear PVC/PVDC aluminium foil blisters.

The tablets are packed in blisters of 10 's.

The pack sizes are 1 x 10 and 3 x 10's in a unit carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: <https://austell.co.za/product-info/>

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