PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL DOSAGE FORMS

CETIRIZINE-HEXAL® 10 mg TABLETS

CETIRIZINE-HEXAL® 1 mg/ml ORAL SOLUTION

CETIRIZINE-HEXAL® 10 mg/ml ORAL DROPS

Cetirizine

CETIRIZINE-HEXAL® 10 mg TABLETS contains sugar (lactose monohydrate 80,0 mg).

CETIRIZINE-HEXAL® 1 mg/ml ORAL SOLUTION contains sorbitol solution 70 %.

CETIRIZINE-HEXAL® 10 mg/ml ORAL DROPS: Sugar free

Read all of this leaflet carefully

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

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

WHAT IS IN THIS LEAFLET

1. What CETIRIZINE-HEXAL is and what it is used for

2. What you need to know before you use CETIRIZINE-HEXAL

3. How to use CETIRIZINE-HEXAL

4. Possible side effects

5. How to store CETIRIZINE-HEXAL

6. Contents of the pack and other information

1. WHAT CETIRIZINE-HEXAL IS AND WHAT IT IS USED FOR

Allergic processes responding to a histamine H_1 receptor antagonist.

– **Respiratory:** Allergic rhinitis, hay fever.

– **Cutaneous:** Allergic skin conditions associated with pruritus e.g. urticaria.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CETIRIZINE-HEXAL

Do not take CETIRIZINE-HEXAL:

- if you are hypersensitive (allergic) to antihistamines such as cetirizine or to any of the other ingredients (listed in section 6).
- if you have severe kidney problems.
- if you are pregnant or breastfeeding as the active ingredient can be excreted into breast milk.
- if the child is under the age of 2 years.

Warnings and precautions

Take special care with CETIRIZINE-HEXAL:

- be careful when drinking alcohol while using CETIRIZINE-HEXAL. It can increase the effects of drinking.
- if you have kidney problems you may need to take a lower dose.
- if you have an enlarged prostate. It may increase the risk of having difficulty-passing water.
- if you are epileptic or are at risk of convulsions (fits).
- if you develop an itchy skin rash or hives.
- if you are having an allergy skin test you need to wait 3 days after taking CETIRIZINE-HEXAL.

Other medicines and CETIRIZINE-HEXAL

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

To date there are no known interactions with other drugs. Studies with azithromycin, cimetidine, diazepam, erythromycin, glipizide, ketoconazole and pseudoephedrine have revealed no evidence of pharmacokinetic interactions. As with other antihistamines it is advisable to avoid excessive alcohol consumption.

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.

Driving and using machines

It is not always possible to predict to what extent CETIRIZINE-HEXAL 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-HEXAL affects them.

CETIRIZINE-HEXAL may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant medicines.

CETIRIZINE-HEXAL 10 mg TABLETS contains lactose monohydrate

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take CETIRIZINE-HEXAL 10 mg TABLETS.

CETIRIZINE-HEXAL 10 mg TABLETS contains lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus.

CETIRIZINE-HEXAL 1 mg/ml ORAL SOLUTION contains sorbitol

If you have been told that you have an intolerance to some sugars, you should not take CETIRIZINE-HEXAL 1 mg/ml ORAL SOLUTION.

3. HOW TO USE CETIRIZINE-HEXAL

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

Tablets:

– Adults, or children 12 years of age or older: one 10 mg tablet daily.

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

Oral solution:

– Adults, or children 12 years of age or older: 10 mg (10 ml) once daily.

– Children 6 to 12 years old: 10 mg (10 ml) daily, either as a single dose or as divided doses of 5 ml in the morning and 5 ml in the evening.

– Children 2 to 6 years old: 5 mg (5 ml) daily, either as a single dose or as divided doses of 2,5 ml in the morning and 2,5 ml in the evening.

Oral drops:

– Adults, or children 12 years of age or older: 10 mg (20 drops) once daily.

– Children 6 to 12 years old: 10 mg (20 drops) daily, either as a single dose or as divided doses of 10 drops in the morning and 10 drops in the evening.

– Children 2 to 6 years old: 5 mg (10 drops) daily, either as a single dose or as divided doses of 5 drops in the morning and 5 drops in the evening.

At present there are no data to suggest that the dose needs to be reduced in elderly patients with normal renal function. In patients with renal insufficiency (creatinine clearance less than 40 ml/min), the dosage should be reduced to half the usual recommended dose. Half the recommended daily dose should be used in patients with moderate to severe hepatic impairment.

If you take more CETIRIZINE-HEXAL 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 can be a symptom of overdosage. Overdosage in children may produce agitation, fatigue, pruritus, rash, somnolence, tachycardia, tremor and urinary retention. Gastric lavage should be performed together with the usual supportive measures in the case of massive overdosage.

There is no specific antidote to date.

Cetirizine is not effectively removed by dialysis.

If you forget to take CETIRIZINE-HEXAL

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

4. POSSIBLE SIDE EFFECTS

CETIRIZINE-HEXAL can have side effects.

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

If any of the following happens, stop using CETIRIZINE-HEXAL 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.
- Fainting.
- Convulsions or fits.

These are all very serious side effects. If you have them, you may have had a serious reaction to CETIRIZINE-HEXAL. 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:

- Changes in the way your heart beats, for example, if you notice it beating faster.
- Less urine than is normal for you.
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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, drowsiness, sleepiness.
- Dry mouth.
- Fatigue.

Less frequent side effects:

- Bleeding or bruising more easily than normal.
- Agitation, aggression, confusion, depression, feeling, hearing or seeing things that are there, difficulty sleeping, tics.
- Dizziness, pins and needles, movement disorders, unusual muscle tone causing distortion of the body, shaking, painful muscle contractions, uncontrollable twitching, jerking or writhing movements.
- Blurred vision, eye movement disorder.
- Stomach pains such as nausea, diarrhoea, digestive disorders.
- Abnormal liver function tests.

- Rash, itching, hives, swelling, itchy spots on limbs or face and may blister.
- Feeling of weakness, generally feeling unwell.
- Weight gain.

Unknown frequency:

- Increased appetite.
- Suicidal thoughts, nightmares.
- Anxiety, nervousness, forgetting things/loss of memory.
- A feeling of dizziness.
- Thickening of mucus.
- Stomach discomfort.
- Skin reaction occurrence due to medication.
- Painful, swollen joints.

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. 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-HEXAL.

Suspected adverse reactions can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. HOW TO STORE CETIRIZINE-HEXAL

Store at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Any unused medicines should be returned to your doctor, pharmacist or health care professional for disposal.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CETIRIZINE-HEXAL contains:

CETIRIZINE-HEXAL 10 mg TABLETS: Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

Inactive ingredients:

Colloidal anhydrous silica, hypromellose, lactose monohydrate, macrogol 4000, magnesium stearate, microcrystalline cellulose, opadry white and titanium dioxide.

CETIRIZINE-HEXAL 1 mg/ml ORAL SOLUTION: Each 1 ml oral solution contains 1 mg cetirizine dihydrochloride.

Inactive ingredients:

Acetic acid 20 %, banana flavour, glycerol 85 %, methyl-parahydroxybenzoate propylene glycol, propyl-parahydroxybenzoate, purified water, saccharin sodium, sodium acetate, sorbitol 70 %.

The oral solution contains methyl-parahydroxybenzoate (0,117 % *m/v)* and propyl-parahydroxybenzoate (0,013 % *m/v)* as preservatives.

CETIRIZINE-HEXAL 10 mg/ml ORAL DROPS: Each 1 ml oral drop contains 10 mg cetirizine dihydrochloride.

Inactive ingredients:

Acetic acid, glycerol 85 %, methyl-parahydroxybenzoate (0,198 % *m/v*), propylene glycol, purified water, saccharin sodium, sodium acetate trihydrate.

The oral drops contain benzoic acid 0,198 % *m/v* as a preservative.

WHAT CETIRIZINE-HEXAL LOOKS LIKE AND CONTENTS OF THE PACK

CETIRIZINE-HEXAL 10 mg TABLETS: Polyvinylchloride/aluminium blister packs of 30's.

CETIRIZINE-HEXAL 1 mg/ml ORAL SOLUTION: 75 ml or 150 ml round brown glass bottles containing 75 ml or 150 ml oral solution respectively. A 5 ml measuring spoon is provided.

CETIRIZINE-HEXAL 10 mg/ml ORAL DROPS: 10 ml or 20 ml brown glass bottles containing 10 ml or 20 ml oral drops respectively.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

THIS LEAFLET WAS LAST REVISED IN

03 February 2021

REGISTRATION NUMBERS

CETIRIZINE-HEXAL® 10 mg TABLETS: 37/5.7.1/0497

CETIRIZINE-HEXAL® 1 mg/ml ORAL SOLUTION: A39/5.7.1/0103

CETIRIZINE-HEXAL® 10 mg/ml ORAL DROPS: 37/5.7.1/0498

[1]Company Reg. No.: 1990/001979/07