CLEAN PROPOSED PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S2

1 NAME OF THE MEDICINE

CETIRIZINE 10 GULF (tablet)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 10 mg cetirizine dihydrochloride

Contains sugar (84 mg lactose/tablet)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cetirizine 10 Gulf is indicated for symptomatic relief of allergic conditions in adults and children 6 years and older such as allergic rhinitis, and allergic skin conditions such as urticaria.

4.2 Posology and method of administration

Adults or children 12 years of age or older: one 10 mg tablet once daily

Children 6 to 12 years old: one 10 mg tablet once daily or 5 mg (half a tablet) twice daily. This dosage form is not suitable for children younger than 6 years.

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 10 Gulf** should be halved.

Dosage in hepatic impairment:

In patients with moderate to severe hepatic impairment, the recommended daily dose of **Cetirizine 10 Gulf** should be halved.

4.3 Contraindications

Hypersensitivity to **Cetirizine 10 Gulf** or any of the ingredients.

Hypersensitivity to hydroxyzine

Cetirizine 10 Gulf is contra-indicated in lactating women, since the active ingredient is excreted in breast-milk.

Cetirizine 10 Gulf is contra-indicated in pregnancy, as safety has not been established.

Children under the age of two years, as safety and efficacy have not been demonstrated.

4.4 Special warnings and precautions for use

Cetirizine 10 Gulf may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant medicines. The patient's ability to perform hazardous activities requiring mental alertness or physical co-ordination such as driving or operating machinery may be impaired.

Porphyria: Use with Caution

Cetirizine 10 Gulf 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 **4.5 Interaction with other medicines and other forms of interaction**).

Laboratory tests: Since **Cetirizine 10 Gulf** may interfere with skin tests for allergy, it must be withdrawn well before such tests are performed.

Contains lactose:

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose should not take **CETIRIZINE 10 GULF**.

4.5 Interactions with other medicines and other forms of interaction

Concomitant use of alcohol and other sedating medicines should be avoided. There is no evidence of an interaction between cetirizine and cimetidine, ketoconazole, erythromycin, azithromycin, diazepam, glipizide, and pseudoephedrine.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established (**see 4.3 CONTRAINDICATIONS).**

Cetirizine is excreted in breast milk

4.7 Effects on ability to drive and use machines

Patients should be warned that some individuals may experience sedation. It is therefore advisable to determine individual response before driving a vehicle or operating machinery. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

4.8 Undesirable Effects

Gastro-intestinal system disorders:

Frequent: nausea, gastro-intestinal discomfort, increased or loss of appetite, dry mouth and constipation or diarrhoea

Respiratory thoracic and mediastinal disorders:

Frequent: thickening of mucous

Ear and labyrinth disorders:

Frequent: tinnitus

Eye disorders:

Frequent: blurred vision, diplopia

Nervous system disorders:

Less frequent: drowsiness, fatigue, dizziness, headache, anxiety, nervousness, asthenia, insomnia and tremors have been reported.

Skin and subcutaneous tissue disorders:

Less frequent: skin rash, urticaria, pruritus, angioedema, photosensitivity, increased sweating

Musculoskeletal, connective tissue and bone disorders:

Less frequent: malaise

Immune system disorders:

Less frequent: anaphylaxis

Hepatobiliary disorders:

Less frequent: urinary retention or frequency and dysuria

4.9 Overdose:

Drowsiness is an expected symptom of overdosage. Overdosage in children may produce agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor and tachycardia. In the case of massive overdosage, gastric lavage should be performed together with usual supportive measures. There is no specific antidote. **Cetirizine 10 Gulf** is not effectively removed by dialysis. FURTHER TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Class

A 5.7.1 Antihistaminics

ATC Code: S01GX12-cetirizine

Cetirizine is a metabolite of hydroxyzine. It is a second generation reversible, competitive inhibitor of histamine at the histamine-1 (H_1) receptor. Cetirizine competes with histamine for the H_1 – receptor site. Cetirizine prevents, but does not, reverse, pharmacological responses mediated by histamine, at the H_1 receptor.

5.2 Pharmacokinetic properties

Cetirizine is well absorbed from the gastro-intestinal tract and peak plasma concentrations are reached within 1 hour after oral administration. Pharmacokinetics are linear, with plasma

concentrations increasing proportionately with increasing doses. The terminal half life in adults is approximately 10 hours; in children aged 6 to 12 years, 6 hours; in children aged 2 to 6 years, 5 hours. Cetirizine is eliminated faster in children, and slower in patients with hepatic or renal impairment (creatinine clearance < 40 ml/min), with a resultant increase in half life and decrease in clearance. Cetirizine does not undergo extensive first pass metabolism. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children.

A high proportion of cetirizine is bound to human plasma proteins.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive ingredients**:** Lactose, starch, polyvinyl pyrrolidone, magnesium stearate

Opadry II – Polyvinyl Alcohol-Part. Hydrolyzed, Titanium Dioxide, Talc, Macrogol/PEG 3350, Lecithin (Soya)

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Blisters & HDPE containers - 24 months when stored at 25 ºC

Patient ready packs – 15 months

6.4 Special precaution for Storage

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.

6.5 Nature and contents of container

- Tablets are packed into clear PVC/ 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

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

Gulf Drug Company (Pty) Ltd

22 Burnside Drive

Old Mill Industrial Park

Mount Edgecombe, 4300

8 REGISTRATION NUMBER(S)

41/5.7.1/0555

9 DATE OF FIRST AUTHORISATION

05/12/2013

10 DATE OF REVISION OF THE TEXT

07/02/2023