SUMMARY OF PRODUCTS CHARACTERISTICS

ZYNCET
(Cetirizine Hydrochloride Syrup 5 mg / 5 ml)

1. Name of the Medicinal Product

1.1 Product name : Zyncet

1.2 Strength : Cetirizine Hydrochloride Syrup 5 mg / 5 ml

1.3 Pharmaceutical Dosage form : Syrup.

2. Qualitative and Quantitative Composition

Label Claim:
Each 5 ml contains:
Cetirizine Hydrochloride BP…….. 5 mg

Please refer Section 6.1 for List of the excipients

3. Pharmaceutical Form

Syrup.
Clear, colourless to pale yellow coloured, banana flavoured slightly viscous liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication(s)

Cetirizine is indicated for the symptomatic treatment of seasonal allergic rhinitis and perennial allergic rhinitis, allergic conjunctivitis, pruritus and urticaria.

4.2 Posology and method of administration

The recommended dosage of Zyncet syrup is:
In children between 2 - 6 years age 5 mg per day given orally either once a day or in two equally divided doses of 2.5 mg 12 hourly.
In children above age of 6 years 10 mg daily given orally either once a day or in two equally divided doses of 5 mg every 12 hours.
The adult dose of Zyncet syrup is 10 mg daily administered orally.
In patients with renal insufficiency dosage should be 1 teaspoonful (5 ml) once daily.

4.3 Contra-indications

Cetirizine syrup is contraindicated in patients with a history of hypersensitivity to any of the constituents.
Cetirizine is contraindicated in lactating women since the active ingredient is excreted in breast milk.

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4.4 Special warnings and precautions for use
Studies in healthy volunteers on 20 and 25 mg/day dose of Cetirizine have not revealed effects on alertness or reaction time. However patients are advised not to exceed the recommended dose if driving or operating machinery.

4.5 Interaction with other medicinal products and other forms of interaction
To date there are no known interactions with other drugs. Studies with Diazepam and Cimetidine have revealed no evidence of interactions. As with other antihistamines, it is advisable to avoid excessive alcohol consumption.

4.6 Fertility, pregnancy and lactation
No adverse effects have been reported from animal studies. There has been little or no use of Cetirizine in pregnancy. As with other drugs, the use of Cetirizine in pregnancy should be avoided.

4.7 Effects on the ability to drive and use machines
Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg.
Patients intending to drive, engage in potentially hazardous activities or operate machinery should not exceed the recommended dose and should take their response to the medicinal product into account.
In sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.8 Undesirable effects

There have been occasional reports of mild and transient subjective adverse effects such as headache, dizziness, drowsiness, agitation, dry mouth and gastro-intestinal discomfort. If desired the dose may be taken as 5 mg in the morning and 5 mg in the evening. In objective tests of psychomotor function, the incidence of sedation with Cetirizine was similar to that of placebo. Occasionally symptoms of hypersensitivity have been reported.

4.9 Overdose
Drowsiness can be a symptom of overdosage, occurring from administration of 50 mg of Cetirizine as a single dose. In the case of massive overdosage, gastric lavage should be performed together with usual supportive measures. To date there is no specific antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antihistaminic
Cetirizine is a potent antihistamine with a low potential for drowsiness at pharmacologically active doses and with additional anti-allergic properties. It is a selective H1- antagonist with negligible effects on the other receptors and so is virtually free from anti-cholinergic and anti-

serotonin effects. Cetirizine inhibits the histamine mediated 'early' phase of allergic reaction and also reduces the migration of inflammatory cells such as eosinophils and the release of mediators associated with the 'late' allergic response.

5.2 Pharmacokinetic properties

Peak blood levels of the order of 0.3 mcg/ml are reached between 30 to 60 minutes after oral administration of a 10 mg dose of Cetirizine. Its plasma half-life is approximately 11 hours. Absorption is very consistent from one subject to the next. Its renal clearance is 30ml/min and the excretion half life is approximately nine hours. Cetirizine is strongly bound to plasma proteins.

5.3 Pre-clinical safety data: N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl Hydroxy Benzoate, Methyl Hydroxy Benzoate, Sodium Acetate Anhydrous, Acetic Acid Glacial, Glycerin, Sucrose, Essence Banana (Bush) No.1.

6.2 Incompatibilities

None known

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Store below 30ºC.

6.5 Nature and contents of container

60 ml Zyncet Syrup is packed in an amber coloured pet bottle. This bottle is sealed with an 'UNICHEM Monogram' printed ROPP Cap. A measuring cup and leaflet is placed with labelled bottle in the carton.

6.6 Special precautions for disposal < and other handling >

No special requirements.

7. Applicant/Manufacturer:

Applicant:
PHILLIPS PHARMACEUTICALS (NIGERIA) LIMITED,
122-132 AFPRINT INDUSTRIAL ESTATE APAPA-
OSHODI EXPRESSWAY, IYANA-ISOLO, LAGOS
NIGERIA.

SUMMARY OF PRODUCTS CHARACTERISTICS

ZYNCET
(Cetirizine Hydrochloride Syrup 5 mg / 5 ml)

Manufacturer:

The Madras Pharmaceuticals
137-B, Old Mahabalipuram
Road, Karapakkam,
Chennai 600 096.

8. Marketing Authorization Number : A4-4773

9. Date of first authorization/renewal of the authorization : June 2020

10. Date of revision of the text: Sep 2024