ULTRAFLOX CAPLET

CIPROFLOXACIN HCL U.S.P 500mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Document type: Summary of Product Characteristics

Document status: Final

Release date: 10th October, 2024

Number of pages: 7 pages

1. NAME OF THE MEDICINAL PRODUCT

CIPROFLOXACIN 500MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains:

CIPROFLOXACIN HCL U.S.P 500mg

Excipients……..……... q.s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

The product is presented as white oblong film coated caplet with "ULTRAFLOX 500" marked on one side and "SAM" marked on the other side.

This is an Oral caplet

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Ciprofloaxacin is fluoroquinolone antibacterial agent with wide spectrum of activity including enterbacteriaceae, Pseudomonas, Aeruginosa, Haemophilus and Neisseria spp. And also against Staphylococci and some other gram positive bacteria. Diseases caused by these bacteria include Gonorrhoea, Tuberculosis, Typhoid, Diarrhoea and Cholera.

4.2 Posology and method of administration.

The recommended dose by oral route is 500mg every 12 hourly. It should be used with caution in patients with epilepsy or history of CNS disorders. Care is necessary in patients with impaired hepatic or renal function.

May be taken with food to minimize upset to stomach; avoid antacids containing magnesium or aluminium or products containing zinc or iron within 4hours before or 2 hours after dosing. May cause dizziness or drowsiness drink fluid liberally.

Posology

Adults:

By mouth, adult, urinary infection 250-500mg every 12 hourly for 7-10days, depending on severity of infection and susceptibility (100mg twice daily for 3days in acute, uncomplicated cystitis in women); lower respiratory tract and skin infection, 500 – 750mg twice daily for 4-6weeks: infections diarrhoea. 500mg every 12hours for 5-7days. Thyphoid fever; 500mg every 12hours for 10days urethral/cervical gonococcal infection; 250-500mg as a single dose (may be combined with doxycycline). Surgical prophylaxis, 750mg 60-90minutes before procedure. Chancroid, 500mg twice daily for 3days.

Elderly:

The use in elderly are associated with an increase risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60years of age. Ciprofloxacin should be used in caution in patients with history of tendon disorders and should be discontinued if the patient experiences pain, swelling, inflammation or rupture of a tendon.

Paediatric population:

Ciprofloxacin is not recommended for use in children and adolescents.

Method of administration

For oral administration

4.3 Contraindications

Ciprofloxacin is not recommended for use in children, adolescent and during pregnancy and in breast feeding mothers because ciprofloxacin have been shown to cause degenerative changes in weight bearing joints of young animals.

4.4 Special warnings and precaution for use.

Ciprofloxacin is not recommended in children below 18year of age; renal impairment avoid excessive alkalinity of urine and ensure adequate fluid intake (risk of crystalluria): prolonged use may result in superinfection.

4.5 Interaction with other medicinal product and other forms of interaction.

Film-coated tablets should be taken 4 hours before or after mineral-containing antacids because these reduce its absorption: co-adminstration with theophyline may lead to raised plasma levels of theophylin. Concomitant administration with Tixanidine.

4.6 Pregnancy and Lactation.

Ciprofloxacin should not be used in pregnancy unless the benefit outweighs the risk and it should not be used in breast-feeding mother.

4.7 Effect on the ability to drive and use machine.

Cuation should be taking because of the drowiness effects.

4.8 Undesirable effect.

Ciprofloxacin is generally well tolerated. The range of adverse effect associated with ciprofloxacin are; Gastrointestial disturbances which include nausea, vomiting, darrhoea, abdominal pain and dyspepsia.

Skin reactions such as rashes and pruritus, hypersensitivity type reaction affecting the skin, vasculitis, erythema multiforme, stevens-johnson sydrome and toxic epiderma necrolysis. Photosencitivity and anaphylaxis have also been reported

CNS disturbances commonest are headache, dizziness and restlessness.

Others include tremor, drowsiness, insomnia, nightmares and visual and other snsory disturbance and more rarely hallucination, psychotic reactions depression and convulsions. Paraethesia and peripheral neuropathy have occurred occasionally.

4.9 Overdose.

In event of acute overdosage, reversible renal toxicity has been reported in some cases. The stomach should be emptied by inducing vomitting or by gastric lavage. The patient should be carefully observed and given supportive treatment including monitoring of renal function, urinary PH and acidity.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Ciprofloxacin belongs to the quinolone carboxylic acid group whose antibacterial action results from the inhibition of bacterial DNA gyrase. On account of its special mechanism of action, there is no parallel resistance to any other antibiotics outside the quinolone carboxlic acid group. It is therefore effective against bacteria resistant e.g to aminoglycosides, penicilins cephalosporin, tetracyclines and others. It is effective against both gram-positive and gram negaive microorganisms. Ureplasma and a few spacies of mycobacterium are less senitive to ciprofloxacin. Combination with other antibacterials results in additive or indifferent effects.

5.2 Pharmacokinetic properties.

Ciprofloxacin is rapidly absorted orally. The mean sputum to plasma ratios of ciprofloxacin is approximately 1. Peak concentrations of ciprofloxacin in sputum were achieved 1.6 (95% CI on mean difference 0.8–2.3) and 1.2 (0.4–1.9) h later than in plasma on day 1 and day 3, respectively (mean difference±95% confidence interval).

The sputum to plasma ratio of ciprofloxacin is approximately 1. The time to peak concentrations of ciprofloxacin in sputum is slightly delayed compared with plasma.

Report has shown residues to be excreted in breast milk, which also makes it unsafe for breastfeeding mother.

5.3 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

Di-calcium phosphate

Lactose

Gelatine

Purified Talc

Magnesium stearate

Methyl paraben

Propyl paraben

Aerosil

6.2 Incompatibilities

Unknown

6.3 Shelf-life

30 Months

6.4 Special precautions for storage

Protect from heat and moisture and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Packs in 10 blisters and put inside a printed white and red folded pack.

7. MARKETING AUTHORISATION HOLDER

SAM PHARMACEUTICALS LIMITED.
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ILORIN,
KWARA STATE, NIGERIA.
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8. MARKETING AUTHORISATION NUMBER(S)

04 – 2232.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 6th December, 2022

10. DATE OF REVISION OF THE TEXT

8th October, 2026