NAME OF THE MEDICINAL PRODUCT

AC-CIPROFLOX CAPLET 500MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each caplet contains:

Ciprofloxacin Hydrochloride..... 500mg

Excipients with known effect:

Each Ciprofloxacin Caplet (500mg) contains Starch and Magnesium Stearate

3. PHARMACEUTICAL FORM

White Caplet.

4. Clinical particulars

4.1 Therapeutic indications

Gastroenteritis - Including cholera, shigellosis, travellers' diarrhoea, campylobacter and *Salmonella enteritis,* typhoid fever; gonorrhea; chancroid; pelvic inflammatory disease (with doxycycline and metronidazole); RTIs; UTIs; bone and joint infections; skin infections; otitis externa; proplylaxis in surgery.

4.2 Posology and method of administration

Use as directed by the physician

4.3 Contraindications

History of tendon disorders related to quinolone use.

4.4 Special warnings and precautions for use

Renal impairment;

Erythematous rashes common in glandular fever, acute or chronic lymphocytic leukaemia, and cytomegalovirus infection.

4.5 Interaction with other medicinal products and other forms of interaction

None Recorded

4.6 Pregnancy and Lactation

May be acceptable. Either animal studies show no risk but human studies not available.

Excreted in breast milk; use with caution.

4.7 Effects on ability to drive and use machines

None Recorded

4.8 Undesirable effects

As with other penicillin, side effect are usually of a mild transitory nature. They may include diarrhea, indigestion or occasionally rashes, either uritcarial which suggests penicillin hypersentivity or erythematous.

An erythematous rash may be caused inpatients with glandular fever, in which case it is advisable to discontinue therapy

4.9 Overdose

None Recorded

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Broad-spectrum penicillin; interferes with bacterial cell wall synthesis during active replication, causing bactericidal activity against susceptible organisms; alternative to amoxicillin when unable to take medication orally.

5.2 Pharmacokinetic properties

Absorption

Peak plasma time: 1-2 hr (oral)

Bioavailability: 30-40%

Distribution

Protein bound: 15-25%

Blister and tissue fluids, bile, and CSF with inflamed meninges

Metabolism

Liver

Elimination

Hlf-life: 1-1.8 hr (normal renal function); 7-20hr (anuria/ end-stage renal disease)

Execretion: Urine (90% within 24hr)

5.3 Preclinical safety data

Non Recorded

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Starch
- Magnesium Stearate

6.2 Incompatibilities

Non Recorded

6.3 Shelf life

- 36 Months from the manufacturing date. Never use after the expiry date clearly indicated on the outer packaging.

6.4 Special precautions for storage

The dry Powder should be stored below 25^0C, once reconstituted the suspension should be used within 7 days of preparation and stored in a cool place, preferably in refrigerators.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Each A.c Ancillin 100ml suspension bottle is placed into a mono pack with a leaflet and a plastic cap.

6.6 Special precautions for disposal <and other handling>

None Recorded

7. <APPLICANT/MANUFACTURER>

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