National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

FOR

ULTRAFLOX CAPLETS BP 500mg

DATE OF FIRST AUTHORIZATION IN NIGERIA: 28th November, 2019

REGISTRATION NUMBER: A11-0958

1. NAME OF THE MEDICINAL PRODUCT

(Ciprofloxacin Tablet) Ciprofloxacin Hydroxide BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film uncoated tablet contains:

Ciprofloxacin hydrochloride BP
Equivalent to Ciprofloxacin……500 mg Excipient……..Q.S.

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Tablets for oral administration.

4. Clinical particulars

4.1 Therapeutic indications

Ciprofloxacin is an antibiotic indicated for a wide range of bacterial infections in adults and children. In adults, it treats lower respiratory tract infections caused by Gram-negative bacteria, including pneumonia and exacerbations of chronic obstructive pulmonary disease, as well as chronic suppurative otitis media, acute exacerbations of chronic sinusitis, urinary tract infections, gonococcal urethritis and cervicitis, epididymo-orchitis, and pelvic inflammatory disease. It is also effective for gastrointestinal infections, intra-abdominal infections, skin and soft tissue infections, malignant external otitis, infections of bones and joints, and for both prophylaxis and treatment of infections in neutropenic patients. Additionally, ciprofloxacin is used for post-exposure prophylaxis and treatment of inhalation anthrax. In children and adolescents, it is indicated for broncho-pulmonary infections caused by Pseudomonas aeruginosa, complicated urinary tract infections, and inhalation anthrax, with treatment reserved for severe cases under the supervision of experienced physicians.

4.2Posology and method of administration Posology

Ciprofloxacin is administered to adults and children with specific dosages depending on the infection type. For lower respiratory tract infections, the typical dosage is 500 mg to 750 mg every 12 hours for 7 to 14 days. Chronic suppurative otitis media and acute exacerbations of chronic sinusitis are treated with 500 mg every 12 hours for 10 to 14 days. For urinary tract infections, the dosage ranges from 250 mg to 500 mg every 12 hours for 7 to 14 days, while

gonococcal urethritis is treated with a single dose of 500 mg. In cases of epididymo-orchitis and pelvic inflammatory disease, 500 mg every 12 hours for 10 to 14 days is recommended, often alongside other therapies. For gastrointestinal infections, 500 mg every 12 hours for 5 to 7 days is typical, and similar dosages apply to intra-abdominal and skin infections. In neutropenic patients, 400 mg every 8 hours may be prescribed, and for inhalation anthrax, 500 mg every 12 hours for 60 days is indicated. In children, broncho-pulmonary infections and complicated urinary tract infections are treated with 10 mg/kg every 12 hours, not exceeding 750 mg and 500 mg, respectively. Ciprofloxacin can be taken with or without food, but dairy products should be avoided around the time of ingestion. Treatment duration varies based on infection severity, and adequate hydration is recommended. Adjustments may be necessary for those with renal impairment, and consultation with a healthcare provider is essential for appropriate monitoring.

4.3 Contraindications

Ciprofloxacin is contraindicated in individuals with a known hypersensitivity to ciprofloxacin or other fluoroquinolones. It should not be used in patients with a history of tendon disorders related to fluoroquinolone use, as it may increase the risk of tendon rupture. Additionally, ciprofloxacin is contraindicated in children and adolescents for routine use due to concerns about articular and cartilage development, except for specific severe infections where benefits outweigh risks. It should also be avoided in patients with a history of myasthenia gravis, as it may exacerbate muscle weakness. Caution is advised in those with a history of seizures or other central nervous system disorders, as ciprofloxacin can lower the seizure threshold. Lastly, it is contraindicated during pregnancy and breastfeeding unless absolutely necessary, as it may affect fetal and infant development.

4.4 Special warnings and precautions for use

Ciprofloxacin 500 mg tablets should be used with caution due to several special warnings and precautions. Patients with a history of tendon disorders, especially those related to fluoroquinolone use, are at increased risk of tendon rupture, particularly in older adults or those on concurrent corticosteroid therapy. It is important to monitor for signs of adverse reactions, including central nervous system effects such as seizures, as ciprofloxacin can lower the seizure threshold. Patients with myasthenia gravis should avoid this medication, as it may worsen muscle weakness. Additionally, caution is advised in patients with renal impairment, as dosage adjustments may be necessary. The risk of QT interval prolongation necessitates careful consideration in patients with a history of cardiac arrhythmias. Lastly, ciprofloxacin should be avoided during pregnancy and breastfeeding unless absolutely required, due to potential risks to fetal and infant development. Regular assessment of the patient's clinical status is essential during treatment to address any emerging concerns.

4.5 Interaction with other medicinal products and other forms of interaction

Ciprofloxacin may interact with several medications and substances, affecting its efficacy and increasing the risk of adverse effects. Notable interactions include antacids and supplements containing calcium, magnesium, aluminum, iron, and zinc, which can significantly reduce ciprofloxacin absorption; it is advised to avoid these within 6 hours before or 2 hours after taking ciprofloxacin. Additionally, ciprofloxacin may enhance the effects of anticoagulants like warfarin, increasing bleeding risk, necessitating frequent monitoring of INR levels. Concurrent use with corticosteroids raises the risk of tendon rupture, especially in older adults. Central nervous system agents, such as NSAIDs and antidepressants, can increase seizure risk when used with ciprofloxacin. The drug can also prolong the QT interval, which may be exacerbated by other QT-prolonging medications, including certain antipsychotics and antiarrhythmics. Furthermore, ciprofloxacin may affect blood glucose levels, potentially causing hypoglycemia or hyperglycemia in patients on antidiabetic medications. Patients should inform their healthcare provider of all medications, supplements, and over-the-counter products they are taking to assess for potential interactions and ensure safe and effective use. Regular monitoring and adjustments may be necessary.

4.6 Pregnancy and Lactation

Pregnancy: The data that are available on administration of ciprofloxacin to pregnant women indicates no malformative or feto/neonatal toxicity of ciprofloxacin. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. In juvenile and prenatal animals exposed to quinolones, effects on immature cartilage have been observed, thus, it cannot be excluded that the drug could cause damage to articular cartilage in the human immature organism / foetus (see section 5.3).
As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy.

Lactation: Ciprofloxacin is excreted in breast milk. Due to the potential risk of articular damage, ciprofloxacin should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Due to its neurological effects, ciprofloxacin may affect reaction time. Thus, the ability to drive or to operate machinery may be impaired.

4.8 Undesirable effects

Ciprofloxacin can cause a range of undesirable effects, which may vary in severity. Common side effects include gastrointestinal disturbances such as nausea, diarrhea, and abdominal pain. Central nervous system effects may manifest as headaches, dizziness, or insomnia, and in some cases, it can lead to more serious issues like seizures or psychiatric reactions, including anxiety or hallucinations. Musculoskeletal problems, particularly tendonitis and tendon rupture, are significant concerns, especially in older adults or those on corticosteroids. Other potential adverse effects include skin reactions, such as rash or photosensitivity, and cardiovascular issues like QT interval prolongation. Rare but severe reactions may involve allergic responses, including anaphylaxis or Stevens-Johnson syndrome. Patients are advised to report any unusual or severe symptoms to their healthcare provider promptly.

4.9 Overdose

An overdose of 12 g has been reported to lead to mild symptoms of toxicity. An acute overdose of 16 g has been reported to cause acute renal failure.

Symptoms in overdose consist of dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment as well as crystalluria and haematuria. Reversible renal toxicity has been reported.

Apart from routine emergency measures it is recommended to monitor renal function, including urinary pH and acidify, if required, to prevent crystalluria. Patients should be kept well hydrated.

Only a small quantity of ciprofloxacin (<10%) is eliminated by haemodialysis or peritoneal dialysis

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic Group: Fluoroquinolones

ATC code: J01MA02

Pharmacodynamics

Ciprofloxacin exhibits pharmacodynamic properties primarily through its mechanism as a fluoroquinolone antibiotic. It acts by inhibiting bacterial DNA gyrase and topoisomerase IV, enzymes crucial for DNA replication, transcription, and repair. This inhibition disrupts bacterial cell division and leads to cell death. Ciprofloxacin is effective against a broad spectrum of Gram-negative and some Gram-positive bacteria, making it suitable for treating various infections, including urinary tract infections, respiratory tract infections, and skin infections. Its bactericidal action is concentration-dependent, meaning that higher drug concentrations lead to increased antibacterial effect. Additionally, ciprofloxacin exhibits post-antibiotic effects, where bacterial growth remains suppressed even after drug levels fall below the minimum inhibitory concentration (MIC). This characteristic contributes to its efficacy and allows for flexible dosing schedules.

5.2 Pharmacokinetic properties

Ciprofloxacin is well-absorbed after oral administration, with bioavailability typically ranging from 70% to 80%. Peak plasma concentrations are achieved within 1 to 2 hours postingestion, and the presence of food may delay absorption but does not significantly affect the overall bioavailability. The drug is widely distributed throughout the body, including in tissues and fluids such as lung tissue, bile, and urine, with a volume of distribution of approximately 2 to 3 L/kg. Ciprofloxacin is approximately 20-40% bound to plasma proteins, primarily albumin.

The elimination half-life of ciprofloxacin is about 4 to 5 hours in healthy adults, allowing for twice-daily dosing. It is primarily excreted unchanged in the urine, accounting for about 4050% of the administered dose, while the remainder is eliminated through feces and bile. Renal impairment can significantly affect its clearance, necessitating dosage adjustments in patients with reduced kidney function. Ciprofloxacin undergoes minimal hepatic metabolism, with cytochrome P450 enzymes playing a minor role in its pharmacokinetics. This profile allows for effective treatment of various bacterial infections while requiring careful monitoring in patients with renal impairment.

5.3 Preclinical safety data Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Dicalcium phosphate
- Maize starch
- Lactose
- Methyl paraben
- Propyl paraben
- Gelatin
- Magnesium stearate
- Purified Talc
- Aerosil
- Film-coating:
- Tab coat white

- API (ISOPROPYL ALCOHOL)
- Macrogol 400
- Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original package in order to protect from moisture

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

1 X10 CAPLETSs in an ALU-PVC blister along with leaflet.

Physical characters:
Film-coated tablet.

White, oval shaped, film, coated caplet with SAM embossed on one side, plain on the other side.

6.6 Special precautions for disposal <and other handling>

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT / MANUFACTURER

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