Summary of Product Characterics

1.17 Product Information

1.17.1 Summary of products characteristics

1. Name of the medicinal product

Strength: 500 mg

INN Name: Ciprofloxacin Tablet USP 500 mg

2. **Qualitative and quantitative composition**

Each Film coated tablet contains,
Ciprofloxacin Hydrochloride USP
Eq. to Ciprofloxacin ..... 500 mg
Excipients..... q.s.

3. **Pharmaceutical form :**

Dosage Form : Tablet

Description :

Aarciflox 500 Tablet is white colored caplet shaped biconvex film coated tablets having break line on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic indications

Aarciflox-500 mg tablets are indicated for the treatment of the following infections.

Adults

- Lower respiratory tract infections due to Gram-negative bacteria
- exacerbations of chronic obstructive pulmonary disease
- broncho-pulmonary infections in cystic fibrosis or in bronchiectasis
- pneumonia
- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria
- Urinary tract infections & Genital tract infections
- Infections of the gastro-intestinal tract (e.g. travellers' diarrhoea)
- Intra-abdominal infections
- Infections of the skin and soft tissue caused by Gram-negative bacteria
- Infections of the bones and joints
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

Children and adolescents

- Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa
- Complicated urinary tract infections and pyelonephritis

4.2 Posology and method of administration

The dose of ciprofloxacin tablets is determined by the severity and type of infection, the sensitivity of the causative organism(s) and the age, weight and renal function of the patient. Treatment may be initiated with tablets according to the condition of the patient.

The following dose recommendations are provided as a guideline and refer to oral dosing only.

Adults: The dose range for adults is 100-750 mg twice daily.

Respiratory tract infections:250-500 mg twice daily

Usual duration of treatment: 7-14 days

Urinary tract infections:

- acute, uncomplicated cystitis in women: 100 mg-250 mg twice daily for three days. Usual duration of treatment: 3 days.

- complicated infections and pyelonephritis: 250-500 mg twice daily. Usual duration of treatment: 7-14days

Prostatitis: 500 mg twice daily. Usual duration of treatment: up to 28 days

Gonorrhoea: acute, uncomplicated: 250-500 mg. Usual duration of treatment: Single Dose.

Severe bacterial enteritis: 500 mg twice daily. Usual duration of treatment: 3-7 days.

Skin and soft tissue infections: 500 mg twice daily. Usual duration of treatment: 5-10 days

Osteomyelitis: 500 mg twice daily. Usual duration of treatment 4 to 6 weeks or longer

Severe systemic infections:500-750 mg twice daily

Children and adolescents (5-17 years):

Acute pulmonary exacerbation of cystic fibrosis caused by Pseudomonas aeruginosa: 40 mg/kg/24 h divided in two doses i.e.20 mg/kg twice daily (maximum 1500 mg daily). Usual duration of treatment: 10-14 days.

4.3 Method of administration

Oral Route of Administration

4.4 Contraindications

CIPROFLOXACIN is contraindicated in persons with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.

4.5 Special warning & precautions for use

Ciprofloxacin monotherapy is not suited for treatment of severe infections and infections that might be due to Gram-positive or anaerobic pathogens. In such infections ciprofloxacin must be co-administered with other appropriate antibacterial agents.

Ciprofloxacin is not recommended for the treatment of streptococcal infections due to inadequate efficacy.

Gonococcal uretritis, cervicitis, epididymo-orchitis and pelvic inflammatory diseases may be caused by fluoroquinolone-resistant Neisseria gonorrhoeae isolates.

Therefore, ciprofloxacin should be administered for the treatment of gonococcal uretritis or cervicitis only if ciprofloxacin-resistant Neisseria gonorrhoeae can be excluded.

Ciprofloxacin should generally not be used in patients with a history of tendon disease/disorder related to quinolone treatment. Quinolones are known to trigger seizures or lower the seizure threshold.

Ciprofloxacin should be used with caution in patients with CNS disorders which may be predisposed to seizure. Cases of hepatic necrosis and life-threatening hepatic failure have been reported with ciprofloxacin.

The use of ciprofloxacin in children and adolescents should follow available official guidance.

Ciprofloxacin treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

PRECAUTIONS

General

Crystals of ciprofloxacin have been observed rarely in the urine of human subjects but more frequently in the urine of laboratory animals, which is usually alkaline. Crystalluria related to ciprofloxacin has been reported only rarely in humans because human urine is usually acidic. Alkalinity of the urine should be avoided in patients receiving ciprofloxacin. Patients should be well hydrated to prevent the formation of highly concentrated urine.

Central Nervous System

Quinolones, including ciprofloxacin, may also cause central nervous system (CNS) events, including: nervousness, agitation, insomnia, anxiety, nightmares or paranoia.

Renal Impairment

Alteration of the dosage regimen is necessary for patients with impairment of renal function.

4.6 Interaction with other medicinal products and other forms of interactions

Ciprofloxacin inhibits CYP1A2 and thus may cause increased serum concentration of concomitantly administered substances metabolised by this enzyme (e.g. theophylline, clozapine, tacrine, ropinirol, tizanidine). Therefore, patients taking these substances concomitantly with ciprofloxacin should be monitored closely for clinical signs of overdose, and determination of serum concentrations, especially of theophylline, may be necessary.

NSAIDs:

Animal trials have shown that concurrent administration of very high doses of a quinolone and certain non steroid anti-inflammatory drugs (NSAIDs) (but not acetyl salicylic acid) may provoke convulsions.

Cyclosporin

A transient increase in the concentration of plasma creatinine is seen when ciprofloxacin and cyclosporine are administered simultaneously. Plasma creatinine concentrations should be checked regularly in these patients.

Oral anticoagulants

Ciprofloxacin, like other quinolones, may enhance the effect of coumarin derivatives including warfarin.

In the case of concomitant administration of these products, prothrombin time (PT) or other suitable coagulation tests should be monitored. If necessary, the oral anticoagulant dosage should be adjusted as appropriate.

Glibenclamide

Simultaneous administration of ciprofloxacin and glibenclamide may increase the effect of glibenclamide.

Probenecid

Probenecid inhibits the renal excretion of ciprofloxacin resulting in an increase of the plasma concentration of ciprofloxacin.

Metoclopramide

Metoclopramide accelerates the absorption of ciprofloxacin. The maximum plasma concentration is therefore achieved more rapidly. The bioavailability of ciprofloxacin is not affected.

Mexiletine

Simultaneous administration of ciprofloxacin and mexiletine can lead to increased plasma concentrations of mexiletine.

Phenytoin

Simultaneous administration of ciprofloxacin and phenytoin may result in increased or reduced serum levels of phenytoin such that monitoring of drug levels is recommended.

Methotrexate

Renal tubular transport of methotrexate may be inhibited by concomitant administration of ciprofloxacin potentially leading to increased plasma levels of methotrexate. This might increase the risk of methotrexate associated toxic reactions. Therefore, patients under methotrexate therapy should be carefully monitored when concomitant ciprofloxacin therapy is indicated.

4.7 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.

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.

4.8 Effects on ability to drive and use machine

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

4.9 Undesirable effects

The most commonly reported adverse drug reactions (ADRs) are nausea and diarrhoea.
The uncommon side effects are fungal superinfections, loss of appetite, hyperactivity or agitation, headache, dizziness, sleeping problems, or taste disorders, vomiting, abdominal pain, digestive problems such as stomach upset, rash, itching, or hives, joint pain in adults, poor kidney function, pains in your muscles and bones, feeling unwell (asthenia), or fever.

4.10 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.

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. 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 Pharmacodynamic Properties

The bactericidal action of ciprofloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair and recombination. The mechanism of action of fluoroquinolones, including ciprofloxacin, is different from that of penicillins, cephalosporins, aminoglycosides, macrolides and tetracyclines; therefore, microorganisms resistant to these classes of drugs may be susceptible to ciprofloxacin. There is no known cross-resistance between ciprofloxacin and other classes of antimicrobials. In vitro resistance to ciprofloxacin develops slowly by multiple-step mutations.

5.2 Pharmacokinetic Properties

Absorption

Ciprofloxacin given as an oral tablet is rapidly and well absorbed from the gastrointestinal tract after oral administration. The absolute bioavailability is approximately 70%, with no substantial loss by first-pass metabolism.

Distribution

The binding of ciprofloxacin to serum proteins is 20% to 40%, which is not likely to be high enough to cause significant protein binding interactions with other drugs.

After oral administration, ciprofloxacin is widely distributed throughout the body. Tissue concentrations often exceed serum concentrations in both men and women, particularly in genital tissue, including the prostate. Ciprofloxacin is present in active form in the saliva, nasal and bronchial secretions, mucosa of the sinuses, sputum, skin blister fluid, lymph, peritoneal fluid, bile, and prostatic secretions.

Ciprofloxacin has also been detected in the lungs, skin, fat, muscle, cartilage and bone. The drug diffuses into the cerebrospinal fluid (CSF); however, CSF concentrations are generally less than 10% of peak serum concentrations. Low levels of the drug have been detected in the aqueous and vitreous humours of the eye.

Biotransformation

Four metabolites have been identified in human urine, which together account for approximately 15% of an oral dose. The metabolites have antimicrobial activity, but are less active than unchanged ciprofloxacin. Ciprofloxacin is an inhibitor of human cytochrome (CY) P450 1A2 (CYP1A2)-mediated metabolism. Co-administration of ciprofloxacin with other drugs primarily metabolized by CYP1A2

results in increased plasma concentrations of these drugs and could lead to clinically significant adverse events of the co-administered drug.

Elimination

The serum elimination half-life in subjects with normal renal function is approximately 4 hours.

Approximately 40% to 50% of an orally administered dose is excreted in the urine as unchanged drug.

After a 250 mg oral dose, urine concentrations of ciprofloxacin usually exceed 200 µg/mL during the first 2 hours, and are approximately 30 µg/mL at 8 to 12 hours after dosing. The urinary excretion of ciprofloxacin is virtually complete within 24 hours after dosing. The renal clearance of ciprofloxacin, which is approximately 300 mL/minute, exceeds the normal glomerular filtration rate of 120 mL/minute. Thus, active tubular secretion would seem to play a significant role in its elimination. Co-administration of probenecid with ciprofloxacin results in about a 50% reduction in the ciprofloxacin renal clearance and a 50% increase in its concentration in the systemic circulation. Although bile concentrations of ciprofloxacin are several-fold higher than serum concentrations after oral dosing, only a small amount of the dose administered is recovered from the bile as unchanged drug. An additional 1% to 2% of the dose is recovered from the bile in the form of metabolites. Approximately 20% to 35% of an oral dose is recovered from the faeces within 5 days after dosing. This may arise from either biliary clearance or transintestinal elimination.

5.3 Preclinical safety data

Non-clinical data reveal no special hazards for humans based on conventional studies of single dose toxicity, repeated dose toxicity, carcinogenic potential, or toxicity to reproduction.

Like a number of other quinolones, ciprofloxacin is phototoxic in animals at clinically relevant exposure levels. Data on photomutagenicity/photocarcinogenicity show a weak photomutagenic or phototumorigenic effect of ciprofloxacin *in-vitro* and in animal experiments. This effect was comparable to that of other gyrase inhibitors.

6. Pharmaceutical Particulars

6.1 List of Excipients

Corn Starch USP
Sodium Starch Glycolate USP
Purified water USP
Magnesium Stearate USP
Purified Talc USP
Colloidal Silicon Dioxide USP
Cross Carmellose Sodium USP
Sheffcoat white IH

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 Months

6.4 Special precaution for storage

Store below 30^0 C. Protect from light.

6.5 Nature and contents of container

Alu-PVC blister of 10 tablets.

6.6 Special precautions for disposal and other handling

No special requirement.

7. Marketing Authorization Holder

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8. Marketing Authorization Number :

MNB/08/730

9. Manufacturer By :
Pinnacle Life Science Pvt. Ltd.
Khasra No. 1328-1330, Village Manpura, Tehsil-Baddi,
Distt. Solan, Himachal Pradesh (H.P.) - 174101, India.

11. Date of first authorization/ renewal of the authorization

20-03-2009

12. Date of the revision of the text

20.08.2021

Patient information Leaflet.

PACKAGE LEAFLET:INFORMATION FOR THE USER

AARCIFLOX 500 (Ciprofloxacin Tablets USP 500 mg)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

– Keep this leaflet. You may need to read it again.

– If you have any further questions, ask your doctor or pharmacist.

– This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

– If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What AARCIFLOX 500 is and what it is used for

Aarciflox-500 mg tablets are indicated for the treatment of the following infections.

Adults

- Lower respiratory tract infections due to Gram-negative bacteria

- exacerbations of chronic obstructive pulmonary disease

- broncho-pulmonary infections in cystic fibrosis or in bronchiectasis

- pneumonia

- Chronic suppurative otitis media

- Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria

- Urinary tract infections & Genital tract infections

- Infections of the gastro-intestinal tract (e.g. travellers' diarrhoea)

- Intra-abdominal infections

- Infections of the skin and soft tissue caused by Gram-negative bacteria

- Infections of the bones and joints

- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

Children and adolescents

- Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa

- Complicated urinary tract infections and pyelonephritis

2. What you need to know before you take AARCIFLOX 500

CIPROFLOXACIN is contraindicated in persons with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.

Ciprofloxacin monotherapy is not suited for treatment of severe infections and infections that might be due to Gram-positive or anaerobic pathogens. In such infections ciprofloxacin must be co-administered with other appropriate antibacterial agents.

Ciprofloxacin is not recommended for the treatment of streptococcal infections due to inadequate efficacy.

Gonococcal uretritis, cervicitis, epididymo-orchitis and pelvic inflammatory diseases may be caused by fluoroquinolone-resistant Neisseria gonorrhoeae isolates.

Therefore, ciprofloxacin should be administered for the treatment of gonococcal uretritis or cervicitis only if ciprofloxacin-resistant Neisseria gonorrhoeae can be excluded.

Ciprofloxacin should generally not be used in patients with a history of tendon disease/disorder related to quinolone treatment. Quinolones are known to trigger seizures or lower the seizure threshold.

Ciprofloxacin should be used with caution in patients with CNS disorders which may be predisposed to seizure. Cases of hepatic necrosis and life-threatening hepatic failure have been reported with ciprofloxacin.

The use of ciprofloxacin in children and adolescents should follow available official guidance.

Ciprofloxacin treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

PRECAUTIONS

General

Crystals of ciprofloxacin have been observed rarely in the urine of human subjects but more frequently in the urine of laboratory animals, which is usually alkaline. Crystalluria related to ciprofloxacin has been reported only rarely in humans because human urine is usually acidic. Alkalinity of the urine should be avoided in patients receiving ciprofloxacin. Patients should be well hydrated to prevent the formation of highly concentrated urine.

Central Nervous System

Quinolones, including ciprofloxacin, may also cause central nervous system (CNS) events, including: nervousness, agitation, insomnia, anxiety, nightmares or paranoia.

Renal Impairment

Alteration of the dosage regimen is necessary for patients with impairment of renal function.

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.

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.

3. HOW TO TAKE AARCIFLOX 500

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The dose of ciprofloxacin tablets is determined by the severity and type of infection, the

sensitivity of the causative organism(s) and the age, weight and renal function of the patient. Treatment may be initiated with tablets according to the condition of the patient.

The following dose recommendations are provided as a guideline and refer to oral dosing only.

Adults: The dose range for adults is 100-750 mg twice daily.

Respiratory tract infections:250-500 mg twice daily

Usual duration of treatment: 7-14 days

Urinary tract infections:

- acute, uncomplicated cystitis in women: 100 mg-250 mg twice daily for three days. Usual duration of treatment: 3 days.

- complicated infections and pyelonephritis: 250-500 mg twice daily. Usual duration of treatment: 7-14days

Prostatitis: 500 mg twice daily. Usual duration of treatment: up to 28 days

Gonorrhoea: acute, uncomplicated: 250-500 mg. Usual duration of treatment: Single Dose.

Severe bacterial enteritis: 500 mg twice daily. Usual duration of treatment: 3-7 days.

Skin and soft tissue infections: 500 mg twice daily. Usual duration of treatment: 5-10 days

Osteomyelitis: 500 mg twice daily. Usual duration of treatment 4 to 6 weeks or longer

Severe systemic infections: 500-750 mg twice daily

Children and adolescents (5-17 years):

Acute pulmonary exacerbation of cystic fibrosis caused by Pseudomonas aeruginosa: 40 mg/kg/24 h divided in two doses i.e.20 mg/kg twice daily (maximum 1500 mg daily). Usual duration of treatment: 10-14 days.

If you take more AARCIFLOX 500 than you should

If you take more than you should, or in the event of an overdose, seek medical advice immediately and, if possible, take any remaining tablets or this leaflet with you to show the doctor.

If you forget to take AARCIFLOX 500.
If you forget to take your medicine take the missed dose as soon as possible and then continue as normal. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. Do not take a double dose to make up for the forgotten one.

If you stop taking AARCIFLOX 500.
long as directed by your doctor. It is important that you complete the course of treatment, even if you begin to feel better after a few days. If you stop taking this medicine too soon, your symptoms may return. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, AARCIFLOX 500 can cause side effects, although not everybody gets them.

The most commonly reported adverse drug reactions (ADRs) are nausea and diarrhoea.

The uncommon side effects are fungal superinfections, loss of appetite, hyperactivity or agitation,

headache, dizziness, sleeping problems, or taste disorders, vomiting, abdominal pain, digestive problems such as stomach upset, rash, itching, or hives, joint pain in adults, poor kidney function, pains in your muscles and bones, feeling unwell (asthenia), or fever.

5. HOW TO STORE AARCIFLOX 500TABLETS

Keep this medicine out of the sight and reach of children. Store below 30°C and keep in the original container. Do not use this medicine after the expiry date which is stated on the label after 'Exp (MM/YY)'. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

5. CONTENTS OF THE PACK AND OTHER INFORMATION

What AARCIFLOX 500 contains
- The active substance is rivaroxaban. Each tablet contains 500 mg of Ciprofloxacin
- The other ingredients are: Tablet core: Corn Starch, Sodium Starch Glycolate, Purified water, Magnesium Stearate, Purified Talc, Colloidal Silicon Dioxide, Cross Carmellose Sodium, Sheffcoat white IH.

What AARCIFLOX 500 looks like and contents of the pack

AARCIFLOX 500 is packed in a Alu-PVC blister of 10 tablets.

Marketing Authorisation Holder

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Manufactured by:

PINNACLE LIFE SCIENCE PVT. LTD.
Khasra No. 1328-1330, Village-Manpura,
Tehsil-Baddi, Dist. Solan,
(H.P.) 174101 India

Labelling

Size : L-83 x W-60 x H-53mm

AARCIFLOX-500

CIPROFLOXACIN TABLET USP

500 mg

Pinnacle Life Science

Contains 10 Blister strips of 10 Tablets Each

AARCIFLOX- 500

Pinnacle Life Science

Code :002-PE-CB-00

AARCIFLOX- 500

Composition :

Each film coated tablet contains :

Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 500 mg.

Excipients q.s.

Dosage :

As directed by the Physician

Storage : Store below 30°C. Protect from light.

Mfg. Lic. No. : MNB/08/729

Batch No. :

Mfg. Date:

Exp. Date:

Read the patient information leaflet before use.

Manufactured by :

Pinnacle Life Science Pvt. Ltd.

Village Manpura, Tehsil Baddi, Distt. Solan (H.P.) INDIA

Pinnacle Life Science

AARCIFLOX- 500

AARCIFLOX-500

CIPROFLOXACIN TABLET USP

500 mg

Pinnacle Life Science

Contains 10 Blister strips of 10 Tablets Each

AARCIFLOX-500

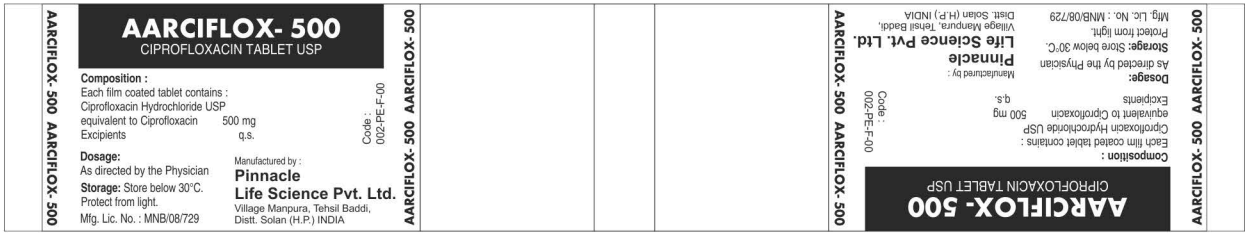
CIPROFLOXACIN TABLET USP

500 mg

Pinnacle Life Science

Contains 10 Blister strips of 10 Tablets Each

Foil Size 164mm Printing Area 154mm
Repeat 30 mm



5mm 50mm 23mm 8 mm 23mm 50mm 5mm

Colour Separation :

Black

For the use of Registered Medical Practitioner or a Hospital or a Laboratory only

AARCIFLOX 500
Ciprofloxacin Tablets USP 500 mg

COMPOSITION
Each film coated tablet contains:
Ciprofloxacin Hydrochloride USP
Equivalent to Ciprofloxacin 500 mg
Excipients…… q.s.

MECHANISM OF ACTION
Ciprofloxacin is a synthetic chemotherapeutic antibiotic of the Fluoroquinolone drug class. It is a second generation Fluoroquinolone antibacterial. It kills bacteria by interfering with the enzymes that cause DNA to rewind after being copied, which stops DNA and protein synthesis.

INDICATION
Ciprofloxacin tablets are indicated for the treatment of the following infections.
Adults
Lower respiratory tract infections due to Gram-negative bacteria
Exacerbations of chronic obstructive pulmonary disease
Broncho-pulmonary infections in cystic fibrosis or in bronchiectasis
Pneumonia
Chronic suppurative otitis media
Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria
Urinary tract infections & Genital tract infections
Infections of the gastro-intestinal tract (e.g. travellers' diarrhoea)
Intra-abdominal infections
Infections of the skin and soft tissue caused by Gram-negative bacteria
Infections of the bones and joints
Inhalation anthrax (post-exposure prophylaxis and curative treatment)
Children and adolescents
Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa
Complicated urinary tract infections and pyelonephritis

DOSAGE AND ADMINISTRATION
The dose of ciprofloxacin tablets is determined by the severity and type of infection, the sensitivity of the causative organism(s) and the age, weight and renal function of the patient. Treatment may be initiated with tablets according to the condition of the patient. The following dose recommendations are provided as a guideline and refer to oral dosing only.

Adults: The dose range for adults is 100-750 mg twice daily.
Respiratory tract infections:250-500 mg twice daily
Usual duration of treatment: 7-14 days
Urinary tract infections:
acute, uncomplicated cystitis in women:
Usual duration of treatment: 3 days. Skin and soft tissue infections: 500 mg twice daily. Usual duration of treatment: 5-10 days Osteomyelitis: 500 mg twice daily.
Usual duration of treatment 4 to 6 weeks or longer Severe systemic infections:500-750 mg twice daily children and adolescents (5-17 years): Prostatitis: 500 mg twice daily. Usual duration of treatment: up to 28 days Gonorrhoea: acute, uncomplicated: 250-500 mg. Usual duration of treatment: Single Dose. Severe bacterial enteritis: 500 mg twice daily. Usual duration of treatment: 3-7 days.

CONTRAINDICATION
CIPROFLOXACIN is contraindicated in persons with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.

WARNING AND PRECAUTIONS
Ciprofloxacin monotherapy is not suited for treatment of severe infections and infections that might be due to Gram-positive or anaerobic pathogens. In such infections ciprofloxacin must be co-administered with other appropriate antibacterial agents.
Ciprofloxacin is not recommended for the treatment of streptococcal infections due to inadequate efficacy.
Gonococcal uretritis, cervicitis, epididymo-orchitis and pelvic inflammatory diseases may be caused by fluoroquinolone-resistant Neisseria gonorrhoeae isolates.Ciprofloxacin should generally not be used in patients with a history of tendon disease/disorder related to quinolone treatment. Quinolones are known to trigger seizures or lower the seizure threshold. Ciprofloxacin should be used with caution in patients with CNS disorders which may be predisposed to seizure. Cases of hepatic necrosis and life-threatening hepatic failure have been reported with ciprofloxacin.Ciprofloxacin treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

PRECAUTIONS
General Crystals of ciprofloxacin have been observed rarely in the urine of human subjects but more frequently in the urine of laboratory animals, which is usually
Central Nervous System : Quinolones, including ciprofloxacin, may also cause central

nervous system (CNS) events, including: nervousness, agitation, insomnia, anxiety, nightmares or paranoia.
Renal Impairment :Alteration of the dosage regimen is necessary for patients with impairment of renal function.

DRUG INTERACTIONS
Ciprofloxacin inhibits CYP1A2 and thus may cause increased serum concentration of concomitantly administered substances metabolised by this enzyme (e.g. theophylline, clozapine, tacrine, ropinirol, tizanidine). Therefore, patients taking these substances concomitantly with ciprofloxacin should be monitored closely for clinical signs of overdose, and determination of serum concentrations, especially of theophylline, may be necessary.
NSAIDs: Animal trials have shown that concurrent administration of very high doses of a quinolone and certain non steroid anti-inflammatory drugs (NSAIDs) (but not acetyl salicylic acid) may provoke convulsions.
Cyclosporin : A transient increase in the concentration of plasma creatinine is seen when ciprofloxacin and cyclosporin are administered simultaneously. Plasma creatinine concentrations should be checked regularly in these patients.
Oral anticoagulants : Ciprofloxacin, like other quinolones, may enhance the effect of coumarinderivatives including warfarin. In the case of concomitant administration of these products, prothrombin time (PT) or other suitable coagulation tests should be monitored. If necessary, the oral anticoagulant dosage should be adjusted as appropriate.
Glibenclamide : Simultaneous administration of ciprofloxacin and glibenclamide may increase the effect of glibenclamide.
Probenecid : Probenecid inhibits the renal excretion of ciprofloxacin resulting in an increase of the plasma concentration of ciprofloxacin.
Metoclopramide : Metoclopramide accelerates the absorption of ciprofloxacin. The maximum plasma concentration is therefore achieved more rapidly. The bioavailability of ciprofloxacin is not affected.
Mexiletine : Simultaneous administration of ciprofloxacin and mexiletine can lead to increased plasma concentrations of mexiletine.Phenytoin : Simultaneous administration of ciprofloxacin and phenytoin may result in increased or reduced serum levels of phenytoin such that monitoring of drug levels is recommended.
Methotrexate : Renal tubular transport of methotrexate may be inhibited by concomitant administration of ciprofloxacin potentially leading to increased plasma levels of methotrexate. This might increase the risk of methotrexate associated toxic reactions. Therefore, patients under methotrexate therapy should be carefully monitored when concomitant ciprofloxacin therapy is indicated.
As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy.

PREGNANCY AND LACTATION:
Pregnancy : 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.

DRIVING: Due to its neurological effects, ciprofloxacin may affect reaction time. Thus, the ability to drive may be impaired.

SIDE EFFECTS:
The most commonly reported adverse drug reactions (ADRs) are nausea and diarrhoea.The uncommon side effects are fungal superinfections, loss of appetite, hyperactivity or agitation, headache, dizziness, sleeping problems, or taste disorders, vomiting, abdominal pain, digestive problems such as stomach upset, rash, itching, or hives, joint pain in adults, poor kidney function, pains in your muscles and bones, feeling unwell (asthenia), or fever.

OVERDOSAGE:
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.In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. 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.

STORAGE : Store below 30°C. Protect from light.

Keep all medicines out of reach of children.

PRESENTATION:
Blister pack of 1x10, 10 x 10, 10x1x10 Tablets.

Manufactured by :
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