

File Information		Artwork Type [PLEASE TICK ✓]		Sign / Stamp	
Product : T ENOXIN TAB 500MG [FRONT] SAP No. : Version : RASUB/V2 Date : 05 July 2024		☐ Unit Box ☐ Outer Box ☐ Label		☒ Leaflet ☐ Fix-A-Form ☐ Others : _____ ☐ Aluminium Foil ☐ Sachet	
Document Category [PLEASE TICK ✓]		Pharmacode / QR Code / Others			
☒ RA Submission Artwork ☐ Internal Artwork Circulation ☐ Others : _____		☐ NPRA Approval Copy ☐ Previous Approved Artwork ☐ Approval Copy Artwork ☐ Draft Artwork			
Remarks		Colour			
Font : Arial Regular (Spacing - 6pt / Size - 6pt) Dimension : 210mm(w) x 297mm(h)		Black 100% Colours shown on this proof are to indicate correct colour separations.			
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enoxin

Tablet 500mg

Ciprofloxacin(HCl) 500mg

PRODUCT DESCRIPTION

An oblong shape tablet, film coated white to off white, one side scored.

COMPOSITION

Each tablet contains 582mg of Ciprofloxacin Hydrochloride (equivalent to 500mg of Ciprofloxacin).
Preservatives: None

PHARMACODYNAMICS

Ciprofloxacin is a fluoroquinolone antibacterial agent with a wide spectrum of activity. It is effective in vitro against pathogens including Enterobacteriaceae, Pseudomonas aeruginosa, Haemophilus, and Neisseria spp. and also against staphylococci and some other Gram-positive bacteria. Ciprofloxacin is bactericidal and acts by inhibiting the A sub unit of DNA gyrase (topoisomerase) which is essential in the reproduction of bacterial DNA.

Spectrum of activity

As a result of in-vitro investigations, the following pathogens can be regarded as sensitive: *E.coli*, *Shigella*, *Salmonella*, *Citrobacter*, *Klebsiella*, *Enterobacter*, *Serratia*, *Hafnia*, *Edwardsiella*, *Proteus* (indole-positive and indole-negative), *Providencia*, *Morganella*, *Yersinia*, *Vibrio*, *Aeromonas*, *Plesiomonas*, *Pasteurella*, *Haemophilus*, *Campylobacter*, *Pseudomonas*, *Legionella*, *Neisseria*, *Moraxella*, *Acinetobacter*, *Brucella*, *Staphylococcus*, *Listeria*, *Corynebacterium* and *Chlamydia*.

The following are sensitive in varying degrees:

Gardnerella, *Flavobacterium*, *Alcaligenes*, *Streptococcus agalactiae*, *Enterococcus faecalis*, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Streptococcus viridans*, *Mycoplasma hominis*, *Mycobacterium tuberculosis* and *Mycobacterium fortuitum*.

The following are generally resistant:

Enterococcus faecium, *Ureaplasma urealyticum*, *Nocardia asteroides*.

Anaerobes, apart from a few exceptions, vary from being moderately sensitive (e.g.

Peptococcus, *Peptostreptococcus*) to resistant (e.g. *Bacteroides*).

Ciprofloxacin is not active against *Trponema pallidum*.

PHARMACOKINETICS

Absorption:

Ciprofloxacin is rapidly and well absorbed from the gastro-intestinal tract. Absorption may be delayed by the presence of food, but is not substantially affected overall.

Time to peak concentration:

A peak plasma concentration of about 2.5 µg/ml is achieved 1 to 2 hours after a dose of 500 mg by mouth.

Distribution:

Plasma protein binding ranges from 20 to 40%. Ciprofloxacin is widely distributed in the body and tissue penetration is generally good. It appears in the cerebrospinal fluid, but concentrations are only about 10% of those in plasma when the meninges are not in flamed. Ciprofloxacin crosses the placenta and is excreted in breast milk. High concentrations are achieved in bile.

Metabolism:

At least 4 active metabolites, which are sulfociprofloxacin, oxociprofloxacin, formylciprofloxacin and desethyleneciprofloxacin, have been identified. The main metabolites are sulfociprofloxacin (faecal metabolite) and oxociprofloxacin (urinary metabolite).

Excretion:

Ciprofloxacin is eliminated principally by urinary excretion, but non-renal clearance may account for about a third of elimination and includes hepatic metabolism, biliary excretion, and possibly transluminal secretion across the intestinal mucosa. Urinary excretion is by active tubular secretion as well as glomerular filtration and is reduced by probenecid. Excretion is virtually complete within 24 hours; about 40 to 50% of an oral dose is excreted unchanged in the urine and about 15% as metabolites. Faecal excretion over 5 days has accounted for 20 to 35% of an oral dose.

INDICATIONS

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Uncomplicated and complicated infections caused by ciprofloxacin susceptible pathogens.

- Infections of respiratory tract: Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E.coli, Pseudomonas, Haemophilus, Moraxella catarrhalis, Legionella and Staphylococcus.
- Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by Gram-negative organisms including Pseudomonas aeruginosa or by staphylococci.
- Infections of the eyes
- Infections of the kidneys and/or the efferent urinary tract.
- Infections of the genital organs, including adnexitis, gonorrhea, prostatitis
- Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis)
- Infections of the skin and soft tissue
- Infections of the bones and joints
- Sepsis
- Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia)
- Selective intestinal decontamination in immunosuppressed patients

Prophylaxis of invasive infections due to Neisseria meningitidis.

Children and adolescents

Ciprofloxacin may be used in children for the second- and third-line treatment of complicated urinary tract infections and pyelonephritis due to Escherichia coli (age range applied in clinical studies: 1 – 17 years) and for the treatment of broncho-pulmonary infections of cystic fibrosis associated with Pseudomonas aeruginosa (age range applied in clinical studies: 5 – 17 years). Treatment should only be initiated after careful benefits/risk evaluation, due to possible adverse events related to joints and/or surrounding tissues.

The clinical trials in children were limited in the indications listed above.

For other indications clinical experience is performed.

Inhalational anthrax (post-exposure) in adults and in children: To reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis.

CONTRAINDICATIONS

Ciprofloxacin must not be used in patients with hypersensitivity to Ciprofloxacin or to other chemotherapeutic agents of the quinolone group. Besides, Ciprofloxacin should not be prescribed to children and adolescents since there is no experience on the drug's safety in these patient groups and since, on the basis of animal studies, it is not entirely improbable that the drug could cause damage to articular cartilage in the immature organism.

Pregnancy and lactation

Ciprofloxacin must not be prescribed for pregnant women, or nursing mothers, since there is no experience on drug's safety in these patient groups and since on the basis of animal studies, it is not entirely improbable that the drug could cause damage to articular cartilage in the immature organism. Animal studies have not shown any evidence of teratogenic effects (malformations).

DRUG INTERACTIONS

The simultaneous administration of ciprofloxacin (oral) and iron, sucralfate, or antacids and highly buffered drugs (e.g. antiretrovirals), containing magnesium, aluminium or calcium reduce the absorption of ciprofloxacin. Consequently, ciprofloxacin should be administered either 1-2 hours before or at least 4 hours after these preparations.

This restriction does not apply to antacids belonging to the class of H2 receptor blockers.

Concurrent administration of ciprofloxacin and theophylline can cause an undesirable increase in the serum theophylline concentration. This can lead to theophylline-induced side-effects; in very rare cases these side effects can be life threatening or fatal. If concurrent use of the two products is unavoidable, the serum theophylline concentration should therefore be checked and the theophylline dose appropriately reduced.

Animal studies have shown that the combination of very high doses of Quinolones (gyrase inhibitors) and certain non-steroidal anti-inflammatory agents (but not acetylsalicylic acid) can provoke convulsions.

A transient rise in the concentration of the serum creatinine was observed when Ciprofloxacin and cyclosporin were administered simultaneously. Therefore, it is necessary to control the serum creatinine concentrations in these patients frequently (twice a week).

The simultaneously administration of ciprofloxacin and warfarin may intensify the action of warfarin. In particular cases, concurrent administration of ciprofloxacin and glibenclamide can intensify the action glibenclamide (hypoglycemia). Probenecid interferes with renal secretion of ciprofloxacin. Co-administration of probenecid and ciprofloxacin increases ciprofloxacin serum concentrations. Metoclopramide accelerates the absorption of ciprofloxacin (oral) resulting in a shorter time to reach maximum plasma concentrations. No effect was seen on the bioavailability of ciprofloxacin.

SIDE EFFECTS/ADVERSE REACTIONS

BODY SYSTEM	ADVERSE DRUG REACTIONS
<i>Incidence of Frequency ≥ 1% < 10%</i> <i>Digestive system</i> Skin and appendages	Nausea, diarrhoea. Rash.
<i>Incidence of Frequency ≥ 0.1% < 1%</i> Body as a whole Cardiovascular system Digestive system Hemic and lymphatic system Metabolic and nutritional disorder Musculo skeletal system Nervous system Skin and appendages Special senses	Abdominal pain, moniliasis, asthenia (general feeling of weakness, tiredness). Thrombo-phlebitis. SGOT increased, SGPT increased,vomiting, dyspepsia, abnormal liver function test, alkaline phosphatase increased, anorexia, flatulence, bilirubinemia. Eosinophilia, leukopenia. Creatinine increased or blood urea nitrogen increased. Arthralgia (joint pain). Headache, dizziness, insomnia, agitation, confusion. Pruritus, maculopapular rash, urticaria. Taste perversion.
<i>Incidence of Frequency ≥ 0.01% < 0.1%</i> Cardiovascular system Digestive system Hemic and lymphatic system Hypersensitivity Metabolic disorders Musculo-Skeletal system Nervous system Respiratory system Skin and appendages Special senses Urogenital system	Tachycardia, migraine, syncope (fainting), vasodilatation (hot flushes). Moniliasis (oral), jaundice, cholestatic jaundice, pseudomembranous colitis. Anaemia, leucopenia. (granulocytopenia), leucocytosis, altered prothrombin values. Thrombocytopenia, thrombocytemia. Thrombocytosis. Allergic reaction, drug fever, anaphylactic reaction. Edema (peripheral, vascular, face), hyperglycemia. Myalgia (muscular pain, joint disorder (joint swelling). Hallucination, sweating, paresthesia (peripheral paralgesia), anxiety, abnormal dreams (nightmares), depression, tremor (trembling), convulsion. Dyspnea, larynxedema. Photosensitivity reaction. Tinnitus, transitory deafness (especially at high frequencies), abnormal vision (visual disturbances), Diplopia, chromatopsia, taste loss (impaired taste). Acute kidney failure, kidney function abnormal, vaginal moniliasis, hematuria, crystalluria, interstitial nephritis.
<i>Incidence of Frequency < 0.01%</i> Cardiovascular system Digestive system Hemic and lymphatic system Hypersensitivity Nervous system Skin and appendages	Vasculitides (petechiae, haemorrhagic, bullae, papules, crust formation). Moniliasis (gastrointestinal), hepatitis. Hemolytic anaemia. Shock (anaphylactic, life threatening), pruritic rash. Grand mal convulsion, abnormal (unsteady) gait. Petechia, erythema multiforme (minor), erythema nodosum.
The most common Adverse Reactions based on spontaneous reports sorted by body system and terms calculated on patient exposure (n = 7790 reported cases)	
<i>Incidence of Frequency < 0.01%</i> Digestive system Hemic and lymphatic system Musculo-Skeletal system Nervous system Skin and appendages Hypersensitivity Special senses Psychiatric reactions	Liver necrosis (very rarely progressing to life threatening hepatic failure), life threatening pseudomembranous colitis with possible fatal outcome. Petechia (punctuate skin, hemorrhages), pancytopenia, agranulocytosis. Tendinitis (predominantly achillo tendinitis); partial or complete tendon rupture (predominantly achilles tendon), exacerbation of symptoms of myasthenia gravis. Psychosis, intracranial hypertension. Steven-Johnson-Syndrome, epidermal necrolysis (Lylell-Syndrome). Serum sickness like reaction. Parosmia (impaired smell), anosmia (usually reversible upon discontinuation). Rare: Depression (potentially culminating in suicidal ideations/ thoughts or suicide attempts and completed suicide) Very Rare: Psychotic reactions (potentially culminating in suicidal ideations/ thoughts or suicide attempts and completed suicide)

Musculoskeletal and connective tissue disorders*

Nervous system disorders*

General disorders and administrative site conditions*

Psychiatric disorders*

Eye disorders*

Ear and labyrinth disorders*

*Very rare cases of prolonged (up to months or years), disabling and potentially irreversible serious drug reactions such as tendinitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia, depression, fatigue, memory impairment, sleep disorders, and impairment of hearing, vision, taste and smell) have been reported in association with the use of fluoroquinolones in some cases irrespective of pre-existing risk factors (see section PRECAUTIONS/WARNING)

Post Marketing Experience Exacerbation

of myasthenia gravis

PRECAUTIONS/WARNINGS

Gastrointestinal system

In the event of severe and persistent diarrhoea during or after treatment a doctor must be consulted since this symptom can hide a serious intestinal disease (life threatening Pseudomembranous colitis with possible fatal outcome), requiring immediate treatment. In such cases ciprofloxacin must be discontinued and appropriate therapy initiated (e.g. Vancomycin, orally 4 x 250 mg/day). Drugs that inhibit peristalsis are contraindicated. There can be a temporary increase in transaminase, alkaline phosphatase or cholestatic jaundice, especially in patients with previous liver damage.

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Nervous system

In epileptic and in patients who have suffered from previous CNS-disorder (e.g. lowered convulsion threshold, previous history of convulsion, reduced cerebral blood flow, altered brain structure or stroke), ciprofloxacin should only be used where the benefits of treatment exceed the risks since these patients are endangered because of possible central nervous side effects.

In some instances the CNS reactions occurred after the first administration. Isolated cases of ciprofloxacin-induced psychoses or depression have been reported, which may progress to self-endangered behavior. In these cases ciprofloxacin has to be discontinued and the doctor should be informed immediately.

Hypersensitivity

In some instances the hypersensitivity and allergic reactions already occurred after the first administration and the doctor should be informed immediately.

Anaphylactic reactions in very rare instances can progress to a life threatening shock, in some instances after the first administration. In these cases Ciprofloxacin has to be discontinued, medical treatment (e.g. treatment for shock) is required.

Musculo-skeletal system

At any sign of tendinitis (e.g. painful swelling) the administration of Ciprofloxacin should be discontinued, physical exercise be avoided and a physician be consulted.

Tendon ruptured (predominantly Achilles tendon) has been reported predominantly in the elderly on prior treatment with glucocorticoids.

Skin and appendages

Ciprofloxacin has been shown to produce photosensitivity reactions. Patients taking Ciprofloxacin should avoid direct exposure to excessive sunlight or UV-light. Therapy should be discontinued if photosensitisation (e.g. Sunburn like skin reactions) occurs.

Ability to drive and use machines

Even when the drug is taken exactly as prescribed, it can affect the speed of reaction to such an extent that the ability to drive or to operate machinery is impaired. This applies particularly in combination with alcohol.

Exacerbation of myasthenia gravis

Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in person with myasthenia gravis. Post marketing serious adverse events, including deaths and requirement for ventilator support have been associated with fluoroquinolones use in persons with myasthenia gravis. Avoid fluoroquinolones in patients with known history of myasthenia gravis.

Aortic aneurysm and dissection

Epidemiologic studies report an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones, particularly in the older population. Therefore, fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease, or in patients diagnosed with pre-existing aortic aneurysm and/or aortic dissection, or in presence of other risk factors or conditions predisposing for aortic aneurysm and dissection (e.g. Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cellarteritis, Behcet's disease, hypertension, known atherosclerosis). In case of sudden abdominal, chest orback pain, patients should be advised to immediately consult a physician in an emergency department.

The use of Ciprofloxacin should be avoided in patients who have experience serious adverse reactions in the past when using fluoroquinolones containing products (see section SIDE EFFECTS/ADVERSE REACTIONS). Treatment of these patients with ciprofloxacin should only be initiated in the absence of alternative treatment options and after careful benefit/risk assessment

Prolonged disabling and potentially irreversible serious adverse drug reactions

Very rare cases of prolonged (continuing months or years), disabling and potentially irreversible serious adverse drug reactions affecting different, sometimes multiple body systems (musculoskeletal, nervous, psychiatric and senses) have been reported in patients receiving fluoroquinolones irrespective of their age and pre-existing risk factors. Ciprofloxacin should be discontinued immediately at the first signs or symptoms of any serious adverse reaction and patients should be advised to contact their prescriber for advice.

Tendinitis and tendon rupture

Tendinitis and tendon rupture (especially but not limited to Achilles tendon), sometime bilateral, may occur as early as within 48 hours of starting treatment with fluoroquinolones and have been reported to occur even up to several months after discontinuation of treatment. The risk of tendinitis and tendon rupture is increased in older patients (above 60 years of age), with renal impairment, patients with solid organ transplants, and those treated concurrently with corticosteroids*. Therefore, concomitant use of corticosteroids should be avoided. At the first sign of tendinitis (e.g. painful swelling, inflammation) the treatment with Ciprofloxacin should be discontinued and alternative treatment should be considered. The affected limb(s) should be appropriately treated (e.g. immobilization). Corticosteroids should not be used if signs of tendinopathy occur.

*[For systemically administered levofloxacin-containing products, the listing of risk factors should additionally include: "in patients receiving daily doses of 1000mg levofloxacin"]

Peripheral neuropathy

Cases of sensory or sensorimotor polyneuropathy resulting in paresthesia, hypaesthesia, dysaesthesia, or weakness have been reported in patients receiving quinolones and fluoroquinolones. Patients under treatment with Ciprofloxacin should be advised to inform their doctor and pharmacist prior to continuing treatment if symptoms of neuropathy such as pain, burning, tingling, numbness, or weakness develop in order to prevent to development of potentially irreversible condition (see section SIDE EFFECTS/ ADVERSE REACTIONS)

Psychiatric reactions

Psychiatric reactions may occur even after the first administration of fluoroquinolones, including Enoxin Tablet 50mg. In rare cases, depression or psychotic reactions can progress to suicidal ideations/thoughts and self-injurious behaviour, such as attempted or completed suicide (see section 'Undesirable effects'). In the event that the patient develops these reactions, Enoxin Tablet 50mg should be discontinued and appropriate measures instituted. Caution is recommended if Enoxin Tablet 50mg is to be used in psychotic patients or in patients with a history of psychiatric disease

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION

Unless otherwise prescribed, the following daily doses are recommended for

Adults

Indications	Daily dose of ciprofloxacin in mg
Infections of the respiratory tract I (according to severity and organism)	2 x 500mg to 2 x 750mg
Urinary tract infections: - Acute, uncomplicated - Cystitis in women (before menopause) - Complicated	2 x 250mg to 2 x 500mg Single dose 500mg 2 x 500mg to 2 x 750mg
Genital infections - Uncomplicated gonorrhea (including extragenital sites of infections) - Adnexitis, prostatitis, epididymo-orchitis	1 x 500mg 2 x 500mg to 2 x 750mg
Diarrhea Other infections (see indications)	2 x 500mg 2 x 500mg
Particularly severe, life-threatening infections, i.e. - Recurrent infections in cystic fibrosis - Bone and joint infections - Septicemia - Peritonitis In particular when Pseudomonas, Staphylococcus or Streptococcus is present	2 x 750mg
Inhalational anthrax (post exposure)	2 x 500mg
Prophylaxis of invasive infections due to Neisseria meningitidis	1 x 500mg as a single dose

Children and adolescent

Indications	Daily dose of ciprofloxacin in mg
Infections in cystic fibrosis	2 x 20mg/kg body weight (maximum of 750mg per dose)
Complicated urinary tract infections and pyelonephritis	2 x 10mg/kg body weight to 2 x 20mg/kg body weight (maximum of 750mg per dose)
Inhalational anthrax (post-exposure)	2 x 15mg/kg body weight (maximum of 500mg per dose)

Missed dose

If a dose is missed, it should be taken as soon as the patient remembers and then treatment should be continued as prescribed. Double doses should not be taken to compensate for a missed dose.

Geriatric patients (>65 years)

Elderly patients should receive a dose as low as possible depending on the severity of their illness and the creatinine clearance (see also 'Patients with renal and hepatic impairment')

Patients with renal and hepatic impairment

Creatinine Clearance [mL/min/1.73m ²]	Serum Creatinine [mg/100mL]	Total daily oral dose of ciprofloxacin
30 to 60	1.4 to 1.9	Maximum 1000mg
Below 30	≥ 2.0	Maximum 500mg

Patients with renal impairment on hemodialysis

- For patients with creatinine clearance between 30 and 60 mL/min/1.73m2(moderate renal impairment) or serum creatinine concentration between 1.4 and 1.9 mg/100 mL, the maximum daily oral dose of ciprofloxacin should be 1000 mg.

- For patients with creatinine clearance less than 30 mL/min/1.73m2(severe renal impairment) or serum creatinine concentration equal or higher than 2.0 mg/100 mL, the maximum daily oral dose of ciprofloxacin should be 500 mg on dialysis days after dialysis

Patients with renal impairment on continuous ambulatory peritoneal dialysis(CAPD)

- The maximum daily oral dose of ciprofloxacin should be (1 x 500 mg EnoxinTablet).

Patients with hepatic impairment

- In patients with impaired hepatic function no dose adjustment is required

Patients with renal and hepatic impairment

- For patients with creatinine clearance between 30 and 60 mL/min/1.73m2 (moderate renal impairment) or serum creatinine concentration between 1.4 and 1.9mg/100mL, the maximum daily oral dose of ciprofloxacin should be 1000mg

- For patients with creatinine clearance less than 30mL/min/1.73m2 (severe renal impairment) or serum creatinine concentration equal or higher than 2.0mg/100mL, the maximum daily oral dose of ciprofloxacin should be 500mg

Children and adolescents

Dosing in children with impaired renal and or hepatic function has not been studied.

Method of administration

For oral use

Enoxin tablets are to be swallowed whole with a small amount of fluid.

Enoxin tablets can be taken independently of mealtimes.

If they are taken on an empty stomach, the active substance is absorbed more rapidly. In this case, Enoxin tablet should not be taken concurrently with dairy products or with mineral-fortified drinks alone (e.g. milk, yoghurt, calcium-fortified orange juice). (see 'Interaction with other medicinal products and other forms of interaction').

Duration of treatment

The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course. It is essential to continue therapy for at least 3 days after disappearance of the fever or of the clinical symptoms.

Mean duration of treatment:

Adults

- 1 day for acute uncomplicated gonorrhoea and cystitis.

- Up to 7 days for infections of the kidneys, urinary tract and abdominal cavity

- A maximum of 2 months for osteomyelitis

- And 7-14 days for all other infections.

- The entire neutropenic phase in immunocompromised patients

In streptococcal infections the treatment must last at least 10 days because of the risk of late complications.

Infections caused by Chlamydia should also be treated for a minimum of 10 days.

Children and adolescent

- Cystic Fibrosis

For broncho-pulmonary infections of cystic fibrosis associated with Pseudomonas aeruginosa infection in pediatric patients (aged 5 –17 years), the duration of treatment is 10 –14 days.

- Complicated Urinary Tract Infections and Pyelonephritis

For complicated urinary tract infections or pyelonephritis due to Escherichia coli, the duration of treatment is 10 –21 days.

Inhalational Anthrax (Post-exposure) in Adults and Children

60 days from the confirmation of Bacillus anthracis exposure.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTE (S)

In the event of acute, excessive oral overdosage, reversible renal toxicity has been reported in some cases.

Therefore apart from routine emergency measures, it is recommended to monitor renal function and to administer Magnesium or Calcium containing antacids which reduce the absorption of ciprofloxacin.

Only small amounts of ciprofloxacin (<10%) is removed by haemodialysis or peritoneal dialysis.

PACKING/PACK SIZE

Blister 10 x 10's.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS

Store in a cool dry place below 30°C.

Protect from light and moisture.

Keep medicines out of reach of children.

Jauhi daripada kanak-kanak.

Shelf life: Please refer to the outer package.

PRODUCT REGISTRATION HOLDER:

Duopharma Marketing Sdn. Bhd.
Lot No. 2, 4, 6, 8 & 10, Jalan P/7,
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Selangor, Malaysia.

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				<table><thead><tr><th>Label</th><th>Description</th><th>Standard</th></tr></thead><tbody><tr><td>W2</td><td>Width of thin code bar</td><td>0.35 mm</td></tr><tr><td>X2</td><td>Width of thick code bar</td><td>1.0 mm</td></tr><tr><td>Y2</td><td>Gap between code bar</td><td>0.65 mm</td></tr><tr><td>Z2</td><td>Height of code bar</td><td>5.0 mm</td></tr></tbody></table> *Dimension stated here is final. Printer to follow AI artwork design accordingly.		Label	Description	Standard	W2	Width of thin code bar	0.35 mm	X2	Width of thick code bar	1.0 mm	Y2	Gap between code bar	0.65 mm	Z2	Height of code bar	5.0 mm
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Pages No : 1 of 2																				

ARTWORK APPROVAL

☒ Local ☐ Export ☐ Share			
☐ For submission only			
☒ For printing only		Approval Date :	
☐ To keep for future printing (KIV SAP Code)			
Old SAP code :		1500010307 N.2	
New SAP code :		1500012042 N.3	
	Sign	Date	
		In	Out
Graphic Designer		03 July 2023	03 July 2023
Regulatory			
Engineering			
Production (Dimension)			
Planner (SAP code)			
Marketing			
Export			
Halal			
QA			
CC#			
Change Control Request No.			

Changes :

1. To add in Pharmacode to full EU requirement.
2. Create new MID code.

SPECIFICATION CHECKLIST

Material & Finishing	☒ Follow existing 1500010307 N.2	☐ N.A
Colour Card :	☐ Yes ☒ No (Before first printing)	☐ N.A
Batch Info :	☐ Pre-Printed ☐ Non-Pre-Printed	☐ N.A
Cartoning :	☐ Auto ☐ Manual-Box	☐ N.A
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Leaflet :	☐ Folded ☐ Non-Folded	☐ N.A

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