Summary of Product Characteristics
ONCINE-500
(Ciprofloxacin Tablets BP 500 mg)

1. Name of the medicinal product

ONCINE-500

Ciprofloxacin Tablets BP 500 mg

2. Qualitative and quantitative composition

Each film-coated tablet contains ciprofloxacin hydrochloride equivalent to 500 mg of ciprofloxacin.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet.

White, caplet-shaped, biconvex film-coated tablets with a break line on one side and plain on the other side. The tablet can be divided into equal doses.

4. Clinical particulars

4.1 Therapeutic indications

Because of the risk of prolonged, disabling and potentially irreversible serious adverse drug reactions (see sections 4.4 and 4.8), ONCINE-500 must only be prescribed when other antibiotics that are commonly recommended for the infection are inappropriate. This applies to all the indications listed below. Situations where other antibiotics are considered inappropriate are where there is resistance to other first-line antibiotics, where other first-line antibiotics are contraindicated in the individual patient, where they have caused side effects requiring treatment to be stopped, or where treatment with them has failed.

ONCINE-500 is indicated for the treatment of the following infections. Special attention should be paid to available information on resistance to ciprofloxacin before commencing therapy.

Adults

Lower respiratory tract infections due to Gram-negative bacteria (exacerbations of chronic obstructive pulmonary disease; broncho-pulmonary infections in cystic fibrosis or bronchiectasis; pneumonia); chronic suppurative otitis media; acute exacerbation of chronic sinusitis, especially if caused by Gram-negative bacteria; uncomplicated and complicated urinary tract infections, acute pyelonephritis and bacterial prostatitis; genital tract infections (gonococcal urethritis and cervicitis, epididymo-orchitis and pelvic inflammatory disease due to susceptible Neisseria gonorrhoeae); gastro-intestinal tract infections (e.g. travellers' diarrhoea) and intra-abdominal infections; infections of the skin and soft tissue caused by Gram-negative bacteria; malignant external otitis; infections of the bones and joints;

prophylaxis of invasive infections due to Neisseria meningitidis; and inhalation anthrax (post-exposure prophylaxis and curative treatment). Ciprofloxacin may be used in the management of neutropenic patients with fever suspected to be due to a bacterial infection.

Children and adolescents

Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa; complicated urinary tract infections and pyelonephritis; and inhalation anthrax (post-exposure prophylaxis and curative treatment). Ciprofloxacin may also be used to treat other severe infections in children and adolescents when this is considered necessary. Treatment should be initiated only by physicians experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

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

4.2 Posology and method of administration

Posology

The dosage is determined by the indication, the severity and site of the infection, the susceptibility of the causative organism(s), the renal function of the patient and, in children and adolescents, the body weight. The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course. Treatment of infections due to certain bacteria (e.g. Pseudomonas aeruginosa, Acinetobacter or staphylococci) may require higher doses and co-administration with other appropriate antibacterial agents.

Adults

Indication	**Daily dose**	**Total duration of treatment**
Lower respiratory tract infections	500 mg to 750 mg twice daily	7 to 14 days
Acute exacerbation of chronic sinusitis; chronic suppurative otitis media	500 mg to 750 mg twice daily	7 to 14 days
Malignant external otitis	750 mg twice daily	28 days up to 3 months
Uncomplicated cystitis	250 mg to 500 mg twice daily	3 days (a 500 mg single dose may be used in pre-menopausal women)
Complicated cystitis, uncomplicated pyelonephritis	500 mg twice daily	7 days
Complicated pyelonephritis	500 mg to 750 mg twice daily	At least 10 days
Prostatitis	500 mg to 750 mg twice daily	2 to 4 weeks (acute); 4 to 6 weeks (chronic)
Gonococcal urethritis and cervicitis	500 mg as a single dose	1 day

Indication	Daily dose	Total duration of treatment
Epididymo-orchitis and pelvic inflammatory disease	500 mg to 750 mg twice daily	At least 14 days
Diarrhoea (bacterial, incl. Shigella spp. other than S. dysenteriae type 1) and severe travellers' diarrhoea	500 mg twice daily	1 day
Diarrhoea due to Shigella dysenteriae type 1	500 mg twice daily	5 days
Diarrhoea due to Vibrio cholerae	500 mg twice daily	3 days
Typhoid fever	500 mg twice daily	7 days
Intra-abdominal infections (Gram-negative)	500 mg to 750 mg twice daily	5 to 14 days
Skin and soft-tissue infections	500 mg to 750 mg twice daily	7 to 14 days
Bone and joint infections	500 mg to 750 mg twice daily	Maximum of 3 months
Neutropenic patients with fever (co-administer with appropriate agent[s])	500 mg to 750 mg twice daily	Duration of neutropenia
Prophylaxis of invasive Neisseria meningitidis infection	500 mg as a single dose	1 day
Inhalation anthrax (post-exposure prophylaxis and curative)	500 mg twice daily	60 days from confirmation of exposure

Paediatric population

Indication	Daily dose	Total duration of treatment
Cystic fibrosis	20 mg/kg body weight twice daily (max. 750 mg per dose)	10 to 14 days
Complicated urinary tract infections and pyelonephritis	10 to 20 mg/kg body weight twice daily (max. 750 mg per dose)	10 to 21 days
Inhalation anthrax	10 to 15 mg/kg body weight twice daily (max. 500 mg per dose)	60 days from confirmation of exposure
Other severe infections	20 mg/kg body weight twice daily (max. 750 mg per dose)	According to the type of infection

Elderly

Elderly patients should receive a dose selected according to the severity of the infection and the patient's creatinine clearance.

Renal impairment

Creatinine clearance (mL/min/1.73 m²)	Serum creatinine (µmol/L)	Oral dose
> 60	< 124	See usual dosage
30 – 60	124 – 168	250–500 mg every 12 hours

Creatinine clearance (mL/min/1.73 m²)	Serum creatinine (µmol/L)	Oral dose
≤ *30*	≥ 169	250–500 mg every 24 hours
Patients on haemodialysis	> 169	250–500 mg every 24 hours (after dialysis)
Patients on peritoneal dialysis	> 169	250–500 mg every 24 hours

In patients with impaired liver function, no dose adjustment is required. Dosing in children with impaired renal and/or hepatic function has not been studied.

Method of administration

Tablets are to be swallowed unchewed with fluid, independent of mealtimes; if taken on an empty stomach, the active substance is absorbed more rapidly. The tablets should not be taken with dairy products (e.g. milk, yoghurt) or mineral-fortified fruit juice (e.g. calcium-fortified orange juice) (see section 4.5). If the patient is unable to take tablets, therapy should be commenced with intravenous ciprofloxacin until a switch to oral administration is possible.

4.3 Contraindications

- Hypersensitivity to the active substance, to other quinolones, or to any of the excipients listed in section 6.1.
- Concomitant administration of ciprofloxacin and tizanidine (see section 4.5).

4.4 Special warnings and precautions for use

The use of ciprofloxacin should be avoided in patients who have experienced serious adverse reactions in the past when using quinolone- or fluoroquinolone-containing products. Treatment of these patients should only be initiated in the absence of alternative treatment options and after careful benefit-risk assessment.

Prolonged, disabling and potentially irreversible serious adverse reactions

Cases of prolonged (continuing for 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 quinolones and fluoroquinolones irrespective of age and pre-existing risk factors. There are no established pharmacological treatments for these symptoms. Ciprofloxacin should be discontinued immediately at the first signs or symptoms of any serious adverse reaction, and patients advised to contact their prescriber, to avoid further exposure which could worsen the reaction.

Aortic aneurysm and dissection, and heart-valve regurgitation/incompetence

Epidemiological studies report an increased risk of aortic aneurysm and dissection (particularly in the elderly) and of aortic and mitral valve regurgitation after intake of fluoroquinolones, sometimes complicated by rupture including fatal cases. Fluoroquinolones should therefore be used only after careful benefit-

risk assessment and consideration of other options in patients with a positive family history of aneurysm or congenital heart-valve disease, or with pre-existing aortic aneurysm/dissection, heart-valve disease, connective-tissue disorders (e.g. Marfan or Ehlers-Danlos syndrome), or other predisposing conditions (e.g. Takayasu arteritis, giant-cell arteritis, hypertension, atherosclerosis, rheumatoid arthritis or infective endocarditis). The risk may be increased with concurrent systemic corticosteroids. Patients should seek immediate medical attention for sudden abdominal, chest or back pain, acute dyspnoea, new-onset palpitations, or abdominal or lower-limb oedema.

Tendinitis and tendon rupture

Tendinitis and tendon rupture (especially of the Achilles tendon), sometimes bilateral, may occur as early as within 48 hours of starting treatment and up to several months after discontinuation. The risk is increased in elderly patients, those with renal impairment, solid-organ transplant recipients, and those treated concurrently with corticosteroids (which should be avoided). Ciprofloxacin should generally not be used in patients with a history of quinolone-related tendon disorder. At the first sign of tendinitis (painful swelling, inflammation), treatment should be discontinued, the affected limb rested, and alternative treatment considered. Ciprofloxacin should be used with caution in patients with myasthenia gravis, as symptoms may be exacerbated.

Central nervous system and psychiatric effects

Ciprofloxacin, like other quinolones, may trigger seizures or lower the seizure threshold, and cases of non-convulsive status epilepticus have been reported; it should be used with caution in patients with CNS disorders predisposed to seizures, and discontinued if seizures occur. Psychiatric reactions may occur even after the first administration; in rare cases, depression or psychosis can progress to suicidal ideation or completed suicide, in which case ciprofloxacin should be discontinued.

Peripheral neuropathy

Cases of sensory or sensorimotor polyneuropathy resulting in paraesthesia, hypoaesthesia, dysaesthesia or weakness have been reported. Patients should be advised to inform their doctor before continuing treatment if symptoms of neuropathy (pain, burning, tingling, numbness or weakness) develop, to prevent the development of a potentially irreversible condition.

Cardiac disorders (QT prolongation)

Caution is required in patients with known risk factors for QT-interval prolongation, such as congenital long-QT syndrome, concomitant use of medicinal products known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics), uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia), or cardiac disease (heart failure, myocardial infarction, bradycardia). Elderly patients and women may be more sensitive. Cases of Kounis syndrome have been reported.

Dysglycaemia

Disturbances in blood glucose, including both hypoglycaemia and hyperglycaemia, have been reported, usually in diabetic patients receiving concomitant oral hypoglycaemic agents (e.g. glibenclamide) or insulin; cases of hypoglycaemic coma have occurred. Careful monitoring of blood glucose is recommended in diabetic patients.

Gastrointestinal effects

Severe and persistent diarrhoea during or after treatment (including several weeks afterwards) may indicate antibiotic-associated colitis (life-threatening, with possible fatal outcome), requiring immediate discontinuation and appropriate therapy; anti-peristaltic medicinal products are contraindicated in this situation.

Hepatobiliary, renal, hypersensitivity and other effects

Cases of hepatic necrosis and life-threatening hepatic failure have been reported; treatment should be discontinued at any sign of hepatic disease (anorexia, jaundice, dark urine, pruritus or tender abdomen). Crystalluria has been reported; patients should be well hydrated and excessive alkalinity of the urine avoided. Hypersensitivity and allergic reactions, including anaphylaxis, may occur after a single dose and may be life-threatening; ciprofloxacin should be discontinued and appropriate treatment given. Haemolytic reactions have occurred in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, in whom ciprofloxacin should be avoided unless the benefit outweighs the risk. Ciprofloxacin has been shown to cause photosensitivity reactions; direct exposure to sunlight or UV light should be avoided during treatment. If vision becomes impaired, an eye specialist should be consulted.

Paediatric population

Ciprofloxacin has been shown to cause arthropathy in the weight-bearing joints of immature animals; in children, arthropathy is reported to occur commonly. Treatment should be initiated only after a careful benefit-risk evaluation and only by physicians experienced in the treatment of cystic fibrosis and/or severe infections in children.

4.5 Interaction with other medicinal products and other forms of interaction

Effects of other products on ciprofloxacin

- Multivalent cations and chelation: multivalent cation-containing products and mineral supplements (calcium, magnesium, aluminium, iron), polymeric phosphate binders (sevelamer, lanthanum carbonate), sucralfate, antacids and highly buffered products (e.g. didanosine) reduce ciprofloxacin absorption. Ciprofloxacin should be taken 1 to 2 hours before, or at least 4 hours after, these preparations. This does not apply to H2-receptor antagonists.

- Dairy products and mineral-fortified drinks (e.g. milk, yoghurt, calcium-fortified juice) taken alone should be avoided, as ciprofloxacin absorption may be reduced.
- Probenecid interferes with renal secretion of ciprofloxacin and increases its serum concentration; omeprazole causes a slight reduction in ciprofloxacin Cmax and AUC; metoclopramide accelerates absorption without affecting bioavailability.

Effects of ciprofloxacin on other products

- Tizanidine must not be given with ciprofloxacin (contraindicated) owing to markedly increased tizanidine concentrations (potentiated hypotension and sedation).
- Theophylline and other xanthines (caffeine, pentoxifylline): serum concentrations may rise to potentially life-threatening levels; monitor and reduce the theophylline dose as necessary.
- Methotrexate: concomitant use is not recommended, as renal tubular transport of methotrexate may be inhibited, increasing its levels and toxicity.
- CYP1A2 substrates (clozapine, olanzapine, ropinirole, duloxetine, agomelatine, zolpidem, lidocaine): concentrations may increase; monitor for adverse effects and adjust doses; concurrent use with zolpidem is not recommended.
- Ciclosporin: a transient increase in plasma creatinine may occur; serum creatinine should be monitored (twice weekly).
- Vitamin K antagonists (e.g. warfarin): the anticoagulant effect may be augmented; monitor the INR during and shortly after co-administration.
- Phenytoin: serum levels may increase or decrease; monitoring is recommended. Sildenafil Cmax and AUC are increased approximately two-fold; use with caution. Drugs prolonging the QT interval should be co-administered with caution (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

The available data on administration of ciprofloxacin to pregnant women indicate no malformative or foeto/neonatal toxicity, and animal studies do not indicate direct or indirect reproductive toxicity. However, as effects on immature cartilage have been observed in juvenile animals exposed to quinolones, damage to articular cartilage in the human foetus cannot be excluded. As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy.

Breast-feeding

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

Fertility

Available data do not indicate an effect of ciprofloxacin on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions are nausea and diarrhoea. The adverse reactions listed below are derived from clinical studies and post-marketing surveillance with ciprofloxacin (oral, intravenous and sequential therapy).

Tabulated list of adverse reactions

Frequency categories are defined as: common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Infections and infestations	Uncommon	Mycotic superinfections
Blood and lymphatic system disorders	Uncommon	Eosinophilia
	Rare	Leukopenia, anaemia, neutropenia, leukocytosis, thrombocytopenia, thrombocytaemia
	Very rare	Haemolytic anaemia, agranulocytosis, pancytopenia (life-threatening), bone-marrow depression (life-threatening)
Immune system disorders	Rare	Allergic reaction, allergic oedema / angioedema
	Very rare	Anaphylactic reaction, anaphylactic shock (life-threatening), serum sickness-like reaction
Endocrine disorders	Not known	Syndrome of inappropriate antidiuretic hormone secretion (SIADH)
Metabolism and nutrition disorders	Uncommon	Decreased appetite
	Rare	Hyperglycaemia, hypoglycaemia
	Not known	Hypoglycaemic coma
Psychiatric disorders	Uncommon	Psychomotor hyperactivity / agitation
	Rare	Confusion and disorientation, anxiety reaction, abnormal dreams, depression (potentially culminating in suicidal ideation, attempted or completed suicide), hallucinations
	Very rare	Psychotic reactions (potentially culminating in suicidal ideation, attempted or completed suicide)
	Not known	Mania, hypomania
Nervous system disorders	Uncommon	Headache, dizziness, sleep disorders, taste disorders

System Organ Class	Frequency	Adverse reaction
	Rare	Paraesthesia and dysaesthesia, hypoaesthesia, tremor, seizures (including status epilepticus), vertigo
	Very rare	Migraine, disturbed coordination, gait disturbance, olfactory nerve disorders, intracranial hypertension and pseudotumor cerebri
	Not known	Peripheral neuropathy and polyneuropathy
Eye disorders	Rare	Visual disturbances (e.g. diplopia)
	Very rare	Visual colour distortions
Ear and labyrinth disorders	Rare	Tinnitus, hearing loss / hearing impaired
Cardiac disorders	Rare	Tachycardia
	Not known	Ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged, Kounis syndrome
Vascular disorders	Rare	Vasodilatation, hypotension, syncope
	Very rare	Vasculitis
Respiratory, thoracic and mediastinal disorders	Rare	Dyspnoea (including asthmatic condition)
Gastrointestinal disorders	Common	Nausea, diarrhoea
	Uncommon	Vomiting, gastrointestinal and abdominal pain, dyspepsia, flatulence
	Rare	Antibiotic-associated diarrhoea (including pseudomembranous colitis)
	Very rare	Pancreatitis
Hepatobiliary disorders	Uncommon	Increase in transaminases, increased bilirubin
	Rare	Hepatic impairment, cholestatic icterus, hepatitis
	Very rare	Liver necrosis (very rarely progressing to life-threatening hepatic failure)
Skin and subcutaneous tissue disorders	Uncommon	Rash, pruritus, urticaria
	Rare	Photosensitivity reactions
	Very rare	Petechiae, erythema multiforme, erythema nodosum, Stevens-Johnson syndrome (potentially life-threatening), toxic epidermal necrolysis (potentially life-threatening)
	Not known	Acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)
Musculoskeletal, connective tissue and bone disorders	Uncommon	Musculoskeletal pain (e.g. extremity pain, back pain, chest pain), arthralgia

System Organ Class	Frequency	Adverse reaction
	Rare	Myalgia, arthritis, increased muscle tone and cramping
	Very rare	Muscular weakness, tendinitis, tendon rupture (predominantly Achilles tendon), exacerbation of symptoms of myasthenia gravis
Renal and urinary disorders	Uncommon	Renal impairment
	Rare	Renal failure, haematuria, crystalluria, tubulointerstitial nephritis
General disorders and administration site conditions	Uncommon	Asthenia, fever
	Rare	Oedema, sweating (hyperhidrosis)
Investigations	Uncommon	Increase in blood alkaline phosphatase
	Rare	Increased amylase
	Not known	International normalised ratio increased (in patients treated with vitamin K antagonists)

Prolonged, disabling and potentially irreversible serious drug reactions (including tendinitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies, depression, fatigue, memory impairment, sleep disorders, and impairment of hearing, vision, taste and smell) have been reported with quinolones and fluoroquinolones, in some cases irrespective of pre-existing risk factors (see section 4.4). Cases of aortic aneurysm and dissection, and of heart-valve regurgitation/incompetence, have also been reported (see section 4.4). In children, arthropathy is reported to occur commonly.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

Symptoms

An overdose of 12 g has been reported to produce mild symptoms of toxicity, and an acute overdose of 16 g to cause acute renal failure. Symptoms of overdose include dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment, and crystalluria and haematuria. Reversible renal toxicity has been reported.

Management

Apart from routine emergency measures (e.g. gastric emptying followed by activated charcoal), renal function should be monitored, including urinary pH, and the urine acidified if required to prevent crystalluria; the patient should be kept well hydrated. Calcium- or magnesium-containing antacids may theoretically reduce the absorption of ciprofloxacin. Only a small quantity of ciprofloxacin (< 10%) is removed by haemodialysis or peritoneal dialysis.

Symptomatic treatment should be implemented, and ECG monitoring undertaken because of the possibility of QT-interval prolongation.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: quinolone antibacterials, fluoroquinolones. ATC code: J01MA02.

Mechanism of action

As a fluoroquinolone antibacterial agent, the bactericidal action of ciprofloxacin results from inhibition of both type II topoisomerase (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair and recombination.

Pharmacokinetic/pharmacodynamic relationship and resistance

Efficacy mainly depends on the relationship between the maximum serum concentration (Cmax) and the minimum inhibitory concentration (MIC), and between the area under the curve (AUC) and the MIC. Resistance may be acquired through a stepwise process by target-site mutations in DNA gyrase and topoisomerase IV, and through impermeability or active efflux; plasmid-mediated resistance encoded by qnr genes has also been reported. The prevalence of acquired resistance may vary geographically and with time, and local information on resistance is desirable, particularly when treating severe infections.

5.2 Pharmacokinetic properties

Absorption

After oral administration, ciprofloxacin is absorbed rapidly and extensively, mainly from the small intestine, reaching maximum serum concentrations 1 to 2 hours later. Single doses of 100 to 750 mg produced dose-dependent Cmax values of 0.56 to 3.7 mg/L, and the absolute bioavailability is approximately 70 to 80%.

Distribution

Protein binding is low (20 to 30%), and ciprofloxacin has a large steady-state volume of distribution of 2 to 3 L/kg. High concentrations are reached in tissues such as lung, sinuses, inflamed lesions and the urogenital tract (urine, prostate, endometrium), often exceeding plasma concentrations.

Biotransformation

Low concentrations of four metabolites (desethylene-, sulpho-, oxo- and formyl-ciprofloxacin) have been reported, which display lower antimicrobial activity than the parent compound. Ciprofloxacin is a moderate inhibitor of CYP1A2.

Elimination

Ciprofloxacin is largely excreted unchanged, both renally and, to a smaller extent, faecally; the serum elimination half-life in subjects with normal renal function is approximately 4 to 7 hours. It undergoes both glomerular filtration and tubular

secretion, and severely impaired renal function increases the half-life to up to 12 hours.

5.3 Preclinical safety data

Non-clinical data reveal no special hazards for humans based on conventional studies of single- and repeated-dose toxicity, carcinogenic potential and reproductive toxicity. Like other quinolones, ciprofloxacin is phototoxic in animals at clinically relevant exposures, with a weak photomutagenic/phototumorigenic effect in vitro and in animal experiments comparable to that of other gyrase inhibitors. As reported for other gyrase inhibitors, ciprofloxacin causes damage to the large weight-bearing joints of immature animals; the extent of cartilage damage varies with age, species and dose and can be reduced by taking weight off the joint, whereas studies in mature animals revealed no cartilage lesions.

6. Pharmaceutical particulars

6.1 List of excipients

- Microcrystalline cellulose
- Maize starch
- Sodium starch glycolate
- Colloidal anhydrous silica
- Purified talc
- Magnesium stearate
- Elegance ELW 1001 white precoat
- Titanium dioxide
- Isopropyl alcohol
- Methylene chloride (dichloromethane)
- Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach of children.

6.5 Nature and contents of container

10 tablets in an Alu-PVC blister; ten blisters (100 tablets) packed in one carton together with a package insert.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder

ZAIN PHARMA LTD

Plot No. 209/13741, Colchester Park, Go-Down No. 1, 2, 3, Off Mombasa Road, P.O. Box 100167-00101, Nairobi, Kenya.

8. Marketing Authorisation Number

CTD12545

9. Date of first authorisation / renewal of the authorisation

03.07.2026

10. Date of revision of the text

03.07.2026