OMNIX O Tablets (Cefixime + Ofloxacin)

Black Box Warning

Serious adverse reactions including tendinitis, tendon rupture, peripheral neuropathy, central nervous system (CNS) effects and exacerbation of myasthenia gravis
See the full prescribing information for complete boxed warning
Fluoroquinolones, including ofloxacin, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including
- tendinitis and tendon rupture;
- peripheral neuropathy; and,
- CNS effects
Discontinue ofloxacin immediately and avoid the use of fluoroquinolones, including ofloxacin in patients who experience any of these serious adverse reactions.
Fluoroquinolones, including ofloxacin, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid ofloxacin in patients with known history of myasthenia gravis.
• Because fluoroquinolones, including ofloxacin, have been associated with serious adverse reactions, reserve ofloxacin for use in patients who have no alternative treatment options for the following indications:
- Acute exacerbation of chronic bronchitis
- Acute uncomplicated cystitis
- Acute sinusitis
This drug may cause low blood sugar and mental health-related side effects.

Qualitative and Quantitative Composition

Each Film coated tablet contains:

Cefixime IP as Trihydrate equivalent to Anhydrous Cefixime……200mg

Ofloxacin IP…….200mg

Colours : Tartrazine & Titanium Dioxide IP

Dosage Form and Strength

Cefixime 200mg and Ofloxacin 200mg Oral tablet

Clinical Particulars

Therapeutic Indications

For the treatment of typhoid fever and urinary tract infection in adults.

Posology and Method of Administration

As directed by the physician.

Contraindications

Cefixime

Cefixime is contraindicated in patients with a known allergy to cefixime or other cephalosporins or any of the other components of the product.

Ofloxacin

The use of ofloxacin is contraindicated as follows:

- Hypersensitivity to the active substance, to any other fluoroquinolone antibacterials, or to any of the excipients.
- In patients with a history of epilepsy or an existing central nervous system (CNS) disorder with a lowered seizure threshold.
- In patients with a history of tendon disorders related to fluoroquinolone administration
- In children or growing adolescents, and in pregnant or breastfeeding women, since animal experiments do not entirely exclude the risk of damage to the growth-plate cartilage in the growing organism cannot be entirely excluded.
- In patients with latent or actual defects in glucose-6-phosphate dehydrogenase activity because they may be prone to haemolytic reactions when treated with quinolone antibacterial agents.

Special Warnings and Precautions for Use

Cefixime

Hypersensitivity Reactions

Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. There is some evidence of partial cross-allergenicity between the penicillins and cephalosporins. Before therapy with cefixime is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefixime occurs, discontinue the drug.

Clostridium difficile-associated Diarrhoea

Clostridium difficile-associated diarrhoea (CDAD) has been reported with the use of nearly all antibacterial agents, including cefixime, and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing isolates of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhoea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile,* and surgical evaluation should be instituted as clinically indicated.

Dose Adjustment in Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing CAPD and haemodialysis. Patients on dialysis should be monitored carefully.

Coagulation Effects

Cephalosporins, including cefixime, may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilised on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Encephalopathy

Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.

Severe Cutaneous Adverse Reactions

Severe cutaneous adverse reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome and drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in some patients on cefixime. When severe cutaneous adverse reactions occur, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs.

Haemolytic Anaemia

Drug-induced haemolytic anaemia, including severe cases with a fatal outcome, has been described for cephalosporins (as a class). The recurrence of haemolytic anaemia after re-administration of cephalosporins in a patient with a history of cephalosporin (including cefixime)-associated haemolytic anaemia has also been reported.

Acute Renal Failure

As with other cephalosporins, cefixime may cause acute renal failure, including tubulointerstitial nephritis as an underlying pathological condition. When acute renal failure occurs, cefixime should be discontinued and appropriate therapy and/or measures should be taken.

Development of Drug-resistant Bacteria

Prescribing cefixime in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Ofloxacin

General

Ofloxacin tablets are not the drug of first choice in pneumonia caused by *Streptococcus pneumoniae* or *Chlamydia pneumoniae*.

Methicillin-resistant S. aureus (MRSA)

These pathogens are very likely to possess co-resistance to fluoroquinolones, including ofloxacin. Therefore ofloxacin is not recommended for the treatment of known or suspected MRSA infections unless laboratory results have confirmed susceptibility of the organism to ofloxacin (and commonly recommended antibacterial agents for the treatment of MRSA-infections are considered inappropriate).

Escherichia coli Resistance

The most common pathogen involved in urinary tract infections, its prevalence varies across the European Union. Prescribers are advised to take into account the local prevalence of resistance in *E. coli* to fluoroquinolones.

Severe Bullous Reactions

Cases of severe bullous skin reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis have been reported with ofloxacin. Patients should be advised to contact their doctor immediately prior to continuing treatment if skin and/or mucosal reactions occur.

Tendonitis

Tendonitis, rarely observed with quinolones, may occasionally lead to rupture involving the Achilles' tendon in particular. Tendinitis and tendon rupture, sometimes bilateral, may occur within 48 hours of starting treatment with ofloxacin and have been reported up to several months after discontinuation of ofloxacin. The risk of tendinitis and tendon rupture is increased in patients aged over 60 years and in patients using corticosteroids. The daily dose should be adjusted in elderly patients based on creatinine clearance. Close monitoring of these patients is therefore necessary if they are prescribed ofloxacin. All patients should consult their physician if they experience symptoms of tendinitis. If tendinitis is suspected, treatment with ofloxacin must be halted immediately, and appropriate treatment (e.g. immobilisation) must be initiated for the affected tendon.

Hypersensitivity

Hypersensitivity and allergic reactions have been reported for fluoroquinolones after first administration. Anaphylactic and anaphylactoid reactions can progress to life-threatening shock, even after the first administration. In these cases, ofloxacin should be discontinued and suitable treatment (e.g. treatment for shock) should be initiated.

Diseases Caused by Clostridium difficile

Diarrhoea, especially if severe, persistent and/or bloody, occurring during or after treatment with

ofloxacin (including several weeks after treatment), may indicate a condition caused by *C. difficile* (CDAD). CDAD may range in severity from mild to life-threatening, the most severe form of which is pseudomembranous colitis. It is, therefore, important to consider this diagnosis in patients who develop serious diarrhoea during or after treatment with ofloxacin. If pseudomembraneous colitis is suspected, treatment should be discontinued immediately. Appropriate specific antibiotic therapy must be started without delay (e.g. oral vancomycin, oral teicoplanin or metronidazole). Medicinal products that inhibit peristalsis are contraindicated in such cases.

Patients Predisposed to Seizures

Quinolones may lower the seizure threshold and may trigger seizures. Ofloxacin is contraindicated in patients with a history of epilepsy or with a known predisposition to seizures. Patients with a known predisposition to seizures may include those with pre-existing CNS lesions, concomitant treatment with fenbufen and similar non-steroidal anti-inflammatory drugs (NSAIDs), or with drugs that lower the cerebral seizure threshold, such as theophylline. In case of convulsive seizures, treatment with ofloxacin should be discontinued.

Patients with Renal Impairment

Since ofloxacin is eliminated primarily via the kidneys, the dose should be adjusted in patients with impaired renal function.

Patients with a History of Psychotic Disorder

Psychotic reactions have been reported in patients receiving fluoroquinolones, including ofloxacin. In some cases, these have progressed to suicidal thoughts or self-endangering behaviour, including suicide attempt, sometimes after a single dose of ofloxacin. In the event that a patient develops these reactions, ofloxacin should be discontinued and appropriate measures instituted.

Ofloxacin should be used with caution in patients with a history of psychotic disorder or in patients with psychiatric disease.

Patients with Hepatic Impairment

Ofloxacin should be used with caution in patients with impaired liver function, as liver damage may occur. Cases of fulminant hepatitis potentially leading to liver failure (including fatal cases) have been reported with fluoroquinolones. Patients should be advised to stop treatment and contact their doctor if signs and symptoms of hepatic disease develop such as anorexia, jaundice, dark urine, pruritus or tender abdomen.

Patients Treated with Vitamin K Antagonists

Due to possible increase in coagulation tests (PT/INR) and/or bleeding in patients treated with fluoroquinolones, including ofloxacin, in combination with a vitamin K antagonist (e.g. warfarin), coagulation tests should be monitored when these drugs are given concomitantly.

Myasthenia gravis

Fluoroquinolones, including ofloxacin, have neuromuscular-blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis. Postmarketing serious adverse reactions, including death and the requirement for respiratory support, have been associated with fluoroquinolone use in patients with myasthenia gravis. Ofloxacin is not recommended in patients with a known history of myasthenia gravis.

Superinfection

As with other antibiotics, the use of ofloxacin, especially if prolonged, may result in overgrowth of non-susceptible organisms, resistant strains of some organisms or *Candida*. Repeated evaluation of the patient's condition is essential and periodic *in vitro* susceptibility tests may be useful. If secondary infection occurs during therapy, appropriate measures should be taken.

Prevention of Photosensitisation

Photosensitisation has been reported with ofloxacin. It is recommended that patients should not expose themselves unnecessarily to strong sunlight or to artificial UV rays (e.g. sunray lamp, solarium), during treatment and for 48 hours following treatment discontinuation in order to prevent photosensitisation.

QT Interval Prolongation

Very rare cases of QT interval prolongation have been reported in patients taking fluoroquinolones. Caution should be taken when using fluoroquinolones, including ofloxacin, in patients with known risk factors for prolongation of the QT interval such as the following:

· Elderly patients and women may be more sensitive to QTc-prolonging medications. Therefore, caution should be taken when using fluoroquinolones, including ofloxacin, in these populations.

· Uncorrected electrolyte imbalance (e.g. hypokalaemia, hypomagnesaemia) – congenital long QT syndrome

· Concomitant use of drugs that are known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics)

· Cardiac disease (e.g. heart failure, myocardial infarction, bradycardia)

Dysglycaemia

As with all quinolones, disturbances in blood glucose, including both hypoglycaemia and hyperglycaemia, have been reported, usually in diabetic patients receiving concomitant treatment with an oral hypoglycaemic agent (e.g. glibenclamide) or with insulin. Cases of hypoglycaemic coma have been reported. In these diabetic patients, careful monitoring of blood glucose is recommended.

Peripheral Neuropathy

Sensory or sensorimotor peripheral neuropathy has been reported in patients receiving fluoroquinolones, including ofloxacin, which can be rapid in its onset. Ofloxacin should be discontinued if the patient experiences symptoms of neuropathy. This would minimise the possible risk of developing an irreversible condition.

Patients with Glucose-6-Phosphate-Dehydrogenase Deficiency

Patients with latent or diagnosed glucose-6-phosphate-dehydrogenase deficiency may be predisposed to haemolytic reactions if they are treated with quinolones. Therefore, if ofloxacin has to be used in these patients, potential occurrence of haemolysis should be monitored.

Interference with Laboratory Tests

In patients treated with ofloxacin, determination of opiates or porphyrin levels in urine may give false-positive results. It may be necessary to confirm positive opiate or porphyrin screens by more specific methods.

Vision Disorders

If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.

Drug Interactions

Cefixime

Carbamazepine

Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Warfarin and Anticoagulants

In common with other cephalosporins, increases in prothrombin times with or without clinical bleeding have been noted in a few patients. Care should, therefore, be taken in patients receiving anticoagulation therapy.

Effects on Laboratory Tests

A false-positive reaction for ketones in the urine may occur with tests using nitroprusside, but not with those using nitroferricyanide.

A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.

A false-positive direct Coomb’s test has been reported during treatment with other cephalosporins; therefore, it should be recognised that a positive Coomb’s test may be due to the drug.

Ofloxacin

Antacids, Sucralfate, Metal Cations

Co-administered magnesium/aluminium antacids, sucralfate, zinc or iron preparations and didanosine chewable/buffered tablets can reduce absorption of ofloxacin tablets. Therefore, ofloxacin should be taken 2 hours before such preparations.

Theophylline, Fenbufen or Similar NSAIDs

No pharmacokinetic interactions of ofloxacin were found with theophylline in a clinical study. However, a pronounced lowering of the cerebral seizure threshold may occur when quinolones are given concurrently with theophylline, NSAIDs, or other agents, which lower the seizure threshold.

Probenecid, Cimetidine, Furosemide, and Methotrexate

Probenecid decreased the total clearance of ofloxacin by 24%, and increased AUC by 16%. The

proposed mechanism is a competition or inhibition for active transport at the renal tubular excretion. Caution should be exercised when ofloxacin is co-administered with drugs that affect the tubular renal secretion such as probenecid, cimetidine, furosemide and methotrexate.

Drugs Known to Prolong QT Interval

Ofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, and antipsychotics).

Vitamin K antagonists

Increased coagulation tests (PT/INR) and/or bleeding, which may be severe, have been reported in patients treated with ofloxacin in combination with a vitamin K antagonist (e.g. warfarin). Coagulation tests should, therefore, be monitored in patients treated with vitamin K antagonists because of a possible increase in the effect of coumarin derivatives.

Glibenclamide

Ofloxacin may cause a slight increase in plasma glibenclamide levels when administered concurrently; it is, therefore, recommended that patients treated concomitantly with ofloxacin and glibenclamide be monitored particularly closely. Since hypoglycaemia is then more likely to occur, close monitoring of blood sugar levels is recommended in such cases.

Use in Special Populations

Pregnant Women

There are no adequate and well-controlled studies in pregnant women.

Lactating Women

There are no adequate and well-controlled studies in lactating women.

Effects on Ability to Drive and Use Machines

Cefixime

In the case of side effects such as encephalopathy (which may include convulsion, confusion, impairment of consciousness, movement disorders), the patient should not operate machines or drive a vehicle.

Ofloxacin

Since there have been occasional reports of drowsiness/somnolence, impairment of skills, dizziness/vertigo and visual disturbances, which may impair the patient's ability to concentrate and react and, therefore, may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery), patients should know how they react to ofloxacin before they drive or operate machinery. These effects may be enhanced by alcohol.

Undesirable Effects

Cefixime

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Cefixime is generally well tolerated. The majority of adverse reactions observed in clinical trials were mild and self-limiting in nature.

The listed adverse reactions mentioned below have been observed during clinical studies and/or during marketed use.

Blood and lymphatic system disorders	Eosinophilia Hypereosinophilia Agranulocytosis Leucopaenia Neutropaenia Granulocytopaenia Haemolytic anaemia Thrombocytopaenia Thrombocytosis
Gastrointestinal disorders	Abdominal pain Diarrhoea* Dyspepsia Nausea Vomiting Flatulence
Hepatobiliary disorders	Jaundice
Infections and infestations	Pseudomembranous colitis
Investigations	Aspartate aminotransferase increased Alanine aminotransferase increased Blood bilirubin increased Blood urea increased Blood creatinine increased
Nervous system disorders	Dizziness Headache Cases of convulsions have been reported with cephalosporins, including cefixime (frequency not known)[**] Beta-lactams, including cefixime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment (frequency not known)[**]
Respiratory, thoracic and mediastinal disorders	Dyspnoea
Renal and urinary disorders	Renal failure acute, including tubulointerstitial nephritis as an underlying pathological condition

Immune system disorders, administrative site conditions, skin and subcutaneous tissue disorders	Anaphylactic reaction Serum sickness-like reaction DRESS Pruritus Rash Drug fever Arthralgia Erythema multiforme Stevens-Johnson syndrome Toxic epidermal necrolysis Angio-oedema Urticaria Pyrexia Face oedema Genital pruritus Vaginitis

*Diarrhoea has been more commonly associated with higher doses. Some cases of moderate-t--severe diarrhoea have been reported; this has occasionally warranted cessation of therapy. Cefixime should be discontinued if marked diarrhoea occurs.

** Cannot be estimated from available data

Postmarketing Experience

The following adverse reactions have been reported following the use of cefixime. Incidence rates were less than 1 in 50 (less than 2%).

· *GASTROINTESTINAL*: Several cases of documented pseudomembranous colitis were identified in clinical trials. The onset of pseudomembranous colitis symptoms may occur during or after therapy.

· *HYPERSENSITIVITY REACTIONS*: Anaphylactic/anaphylactoid reactions (including shock and fatalities), skin rashes, urticaria, drug fever, pruritus, angio-oedema, and facial oedema. erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported.

· *HEPATIC*: Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, and jaundice.

· *RENAL*: Transient elevations in BUN or creatinine, acute renal failure.

· *CNS*: Headaches, dizziness, seizures.

· *HAEMIC AND LYMPHATIC SYSTEM*: Transient thrombocytopaenia, leucopaenia, neutropaenia, prolongation in prothrombin time, elevated LDH, pancytopaenia, agranulocytosis, and eosinophilia.

· *ABNORMAL LABORATORY TESTS:* Hyperbilirubinaemia.

Other Adverse Reactions

Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis. Spontaneous reported cases of acute generalised exanthematous pustulosis (AGEP) associated with the treatment using cefixime deduce that there is a potential risk for systemic involvement in patients with AEGP.

Adverse Reactions Reported for Cephalosporin-class Drugs

Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction, including cholestasis, aplastic anaemia, haemolytic anaemia, haemorrhage, and colitis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

Ofloxacin

The information given below is based on data from clinical studies and on extensive postmarketing experience.

System Organ Class	**Uncommon (≥1/1,000 to <1/100)**	**Rare (≥1/10,000 to <1/1,000)**	**Very rare (<1/10,000)**	**Not Known (cannot be estimated from available data)***
Infections and infestations	Fungal infection Pathogen resistance			
Blood and lymphatic system disorders			Anaemia Haemolytic anaemia Leucopaenia Eosinophilia Thrombocytopaenia	Agranulocytosis Bone marrow failure Pancytopaenia
Immune system disorders		Anaphylactic reaction* Anaphylactoid reaction* Angio-oedema*	Anaphylactic shock* Anaphylactoid shock*	
Metabolism and nutrition disorders		Anorexia		Hypoglycaemia in diabetics treated with hypoglycaemic agents Hyperglycaemia, hypoglycaemic coma
Psychiatric disorders	Agitation, Sleep disorder Insomnia	Psychotic disorder (e.g. hallucination) Anxiety Confusional state Nightmares Depression		Psychotic disorder and depression with self-endangering behaviour, including suicidal ideation or suicide attempt Nervousness

Nervous system disorders	Dizziness Headache	Somnolence Paraesthesia Dysgeusia Parosmia	Peripheral sensory neuropathy* Peripheral sensory motor neuropathy* Convulsion* Extra-pyramidal symptoms or other disorders of muscular coordination	Tremor Dykinesia Ageusia Syncope
Eye disorders	Eye irritation	Visual disturbance		Uveitis
Ear and labyrinth disorders	Vertigo		Tinnitus Hearing loss	Hearing impaired
Cardiac disorders		Tachycardia		Ventricular arrhythmias and *torsades de pointes* (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged
Vascular disorders		Hypotension		
Respiratory, thoracic and mediastinal disorders	Cough Nasopharyngitis	Dyspnoea Bronchospasm		Allergic pneumonitis Severe dyspnoea
Gastrointestinal disorders	Abdominal pain Diarrhoea Nausea Vomiting	Enterocolitis, sometimes haemorrhagic	Pseudomembranous colitis*	Dyspepsia Flatulence Constipation Pancreatitis
Hepatobiliary disorders		Hepatic enzymes increased (ALAT, ASAT, LDH, gamma-GT and/or alkaline phosphatase) Blood bilirubin increased	Jaundice cholestatic	Hepatitis, which may be severe* Severe liver injury, including cases with acute liver failure, sometimes fatal, have been reported with ofloxacin, primarily in patients with underlying liver disorders

Skin and subcutaneous tissue disorders	Pruritus Rash	Urticaria Hot flushes Hyperhidrosis Pustular rash	Erythema multiforme Toxic epidermal necrolysis Photosensitivity reaction* Drug eruption Vascular purpura Vasculitis, which can lead, in exceptional cases, to skin necrosis	Stevens-Johnson syndrome Acute generalised exanthemous pustulosis Drug rash Stomatitis Exfoliative dermatitis
Musculoskeletal and connective tissue disorders		Tendonitis	Arthralgia Myalgia Tendon rupture (e.g. Achilles' tendon) which may occur within 48 hours of treatment start and may be bilateral	Rhabdomyolysis and/or myopathy Muscular weakness Muscle tear Muscle rupture Ligament rupture Arthritis
Renal and urinary disorders		Serum creatinine increased	Acute renal failure	Acute interstitial nephritis
Congenital, familial and genetic disorders				Attacks of porphyria in patients with porphyria
General disorders and administration site conditions				Asthenia Pyrexia Pain (including pain in back, chest and extremities)

* Postmarketing experience

The drug may cause low blood sugar and mental health-related side effects. Low blood sugar levels, also called hypoglycaemia, can lead to coma. The mental health-related side effects more prominent and more consistent across the systemic fluoroquinolone drug class are as mentioned below:

- Disturbances in attention
- Disorientation
- Agitation
- Nervousness
- Memory impairment

Serious disturbances in mental abilities (delirium)

Reporting of Suspected Adverse Reactions

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme of India (PvPI) by calling on 1800 267 7779 (Cipla number) or you can report to PvPI on 1800 180 3024. By reporting side effects, you can help provide more information on the safety of this product.

Overdose

Cefixime

There is no experience with overdoses with cefixime. Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by haemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of cefixime did not differ from the profile seen in patients treated at the recommended doses.

Ofloxacin

Symptoms

The most important signs to be expected following acute overdose are CNS symptoms such as confusion, dizziness, impairment of consciousness and convulsive seizures, increases in QT interval, as well as gastrointestinal reactions such as nausea and mucosal erosions.

CNS effects, including confusional state, convulsion, hallucination and tremor, have been observed in postmarketing experience.

Management

In the case of overdose, taking appropriate measures to remove any unabsorbed ofloxacin, e.g. gastric lavage, administration of adsorbants and sodium sulphate, if possible during the first 30 minutes, are recommended; antacids are recommended for protection of the gastric mucosa.

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation. Antacids may be used for protection of gastric mucosa. A fraction of ofloxacin may be removed from the body with haemodialysis. Peritoneal dialysis and CAPD are not effective in removing ofloxacin from the body. No specific antidote exists.

Elimination of ofloxacin may be increased by forced diuresis.

Pharmacological Properties

Mechanism of Action

Cefixime

As with other cephalosporins, the bactericidal action of cefixime results from inhibition of cell wall synthesis. Cefixime is stable in the presence of certain beta-lactamase enzymes. As a result, certain organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases may be susceptible to cefixime.

Ofloxacin

Ofloxacin inhibits bacterial DNA replication by inhibiting bacterial topoisomerases, particularly DNA gyrase and topoisomerase IV. It is active after oral administration.

Therapeutic doses of ofloxacin are devoid of pharmacological effects on the voluntary or autonomic nervous system.

Pharmacodynamic Properties

Cefixime

Pharmacotherapeutic group: third-generation cephalosporin, ATC code: J01DD08

Cefixime is an oral third-generation cephalosporin that has marked *in vitro* bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms.

Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens, including *Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Klebsiella* species, *Haemophilus influenzae* (beta-lactamase-positive and -negative), *Branhamella catarrhalis* (beta-lactamase-positive and -negative) and *Enterobacter* species. It is highly stable in the presence of beta-lactamase enzymes.

Resistance

Resistance to cefixime in isolates of *Haemophilus influenzae* and *Neisseria gonorrhoeae* is most often associated with alterations in penicillin-binding proteins (PBPs). Cefixime may have limited activity against Enterobacteriaceae-producing extended-spectrum beta-lactamases (ESBLs). *Pseudomonas* species, *Enterococcus* species, strains of Group D streptococci, *Listeria monocytogenes,* most strains of staphylococci (including methicillin-resistant strains), most strains of *Enterobacter* species, most strains of *Bacteroides fragilis,* and most strains of *Clostridium* species are resistant to cefixime.

Antimicrobial Activity

Cefixime has been shown to be active against most isolates of the following bacteria both *in vitro* and in clinical infections:

GRAM-POSITIVE BACTERIA

Streptococcus pneumoniae

Streptococcus pyogenes

GRAM-NEGATIVE BACTERIA

Haemophilus influenzae (beta-lactamase-positive and -negative)

Moraxella catarrhalis

Escherichia coli

Proteus mirabilis

Neisseria gonorrhoeae

Also, clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens, including *Branhamella catarrhalis* (beta-lactamase-positive and -negative) and *Enterobacter* species.

The following *in vitro* data are available, but their clinical significance is unknown. At least 90% of the following bacteria exhibit an *in vitro* minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for cefixime against isolates of similar genus or organism group. However, the efficacy of cefixime in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

GRAM-POSITIVE BACTERIA

Streptococcus agalactiae

GRAM-NEGATIVE BACTERIA

Citrobacter amalonaticus

Citrobacter diversus

Haemophilus parainfluenzae

Klebsiella oxytoca

Klebsiella pneumoniae

Pasteurella multocida

Proteus vulgaris

Providencia species

Salmonella species

Serratia marcescens

Shigella species

Ofloxacin

- Pharmacotherapeutic group: Quinolone Antibacterials, Fluoroquinolones
- ATC code: J01 MA 01

The NCCLS MIC breakpoint recommendations are as follows:

S ≤2 mg/l and R ≥1 mg/l

Haemophilus influenzae and *Neisseria gonorrhoea* are exceptions with breakpoints at S ≤0.25 mg/l and R ≥1 mg/l

The BSAC general recommendations are S ≤2 mg/l and R ≥4 mg/l

According to DIN 58 940, the following limits apply for ofloxacin:

S ≤1 mg/L, I = 2 mg/L, R ≥4 mg/L.

The prevalence of resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. This information gives only an approximate guidance on probabilities whether microorganisms will be susceptible to ofloxacin or not. Only those pathogens relevant to the indications are listed.

	European Range of Acquired Bacterial Resistance to Ofloxacin
Normally Susceptible	
Aerobic Gram-positive microorganisms	
S. aureus – methicillin-sensitive	0.3 to 12.6%
S. pyogenes	2 to 5%
Aerobic Gram-negative microorganisms	
Acinetobacter spp.	0.3 to 7.3%
Citrobacter spp.	3 to 15%
Enterobacter spp.	2 to 13%
E. coli	1 to 8%
H. influenzae	1%
Klebsiella spp.	1 to 10%
Moraxella spp.	0 to 0.2%
Morganella morganii	0 to 6.9%
N. gonorrhoeae	25%
Proteus spp.	1 to 15%
Serratia marcescens	2 to 2.4%
Others	
Chlamydia spp.	
L. pneumophila	
Intermediately susceptible	
Aerobic Gram-positive microorganisms	
S. pneumoniae	70%
Providentia	17.1%
Aerobic Gram-negative microorganisms	
E. faecalis	50%
P. aeruginosa	20 to 30%
Serratia spp.	20 to 40%
Stenotrophomonas maltophilia	5.1 to 11%
Others	
Mycoplasma spp.	0 to 5.3%
Ureaplasma spp.	0 to 2.1%

Resistant	
Anaerobic bacteria	
S. aureus – methicillin-resistant	69.2 to 85.7%
T. pallidum	

Resistance

The main mechanism of bacterial resistance to ofloxacin involves one or more mutations in the target enzymes, which generally confer resistance to other active substances in the class. Efflux pump and impermeability mechanisms of resistance have also been described and may confer variable resistance to active substances in other classes.

Pharmacokinetic Properties

Cefixime

The absolute oral bioavailability of cefixime is in the range of 22 to 54%. Absorption is not significantly modified by the presence of food. Cefixime may, therefore, be given without regard to meals.

From *in vitro* studies, serum or urine concentrations of 1 mcg/mL or greater were considered to be adequate for most common pathogens against which cefixime is active. Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mcg/mL. Little or no accumulation of cefixime occurs following multiple dosing.

The pharmacokinetics of cefixime was evaluated in healthy elderly (age >64 years) and young volunteers (age 11 to 35 years) by comparing the administration of 400 mg doses once daily for 5 days. Mean C_{max} and AUC values were slightly greater in the elderly. Elderly patients may be given the same dose as the general population.

Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine.

Serum protein-binding is well characterised for human and animal sera; cefixime is almost exclusively bound to the albumin fraction, with the mean free fraction being approximately 30%. Protein-binding of cefixime is only concentration-dependent in human serum at very high concentrations, which are not seen following clinical dosing.

Transfer of ^{14}C-labelled cefixime from lactating rats to their nursing offspring through breast milk was quantitatively small (approximately 1.5% of the mothers' body content of cefixime in the pup). No data are available on secretion of cefixime in human breast milk. Placental transfer of cefixime was small in pregnant rats dosed with labelled cefixime.

Ofloxacin

The administration of oral doses to fasting volunteers was followed by a rapid and almost complete absorption of ofloxacin. The peak plasma concentration after a single oral dose of 200 mg averaged 2.6 µg/ml and was reached within 1 hour.

The plasma elimination half-life was 5.7 to 7.0 hours and was not dose-related. The apparent distribution volume was 120 litres. The plasma concentration did not materially rise with repeat doses (accumulation factor for twice daily dosage: 1.5). The plasma protein-binding was approx. 25%.

The biotransformation of ofloxacin was below 5%. The two main metabolites found in the urine were N-desmethyl-ofloxacin and ofloxacin-N-oxide.

Excretion is primarily renal. Between 80 and 90% of the dose were recovered from the urine as unchanged substance.

Ofloxacin was present in the bile in glucuronidised form. The pharmacokinetics of ofloxacin after intravenous infusion is very similar to those after oral doses. The plasma half-life is prolonged in persons with renal impairment; total and renal clearance decrease in accordance with the creatinine clearance. In renal impairment, the dose should be reduced.

No clinically relevant interactions were seen with food and no interaction was found between ofloxacin and theophylline.

Non-Clinical Properties

Animal Toxicology or Pharmacology

Cefixime

Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. Cefixime did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage *in vitro* and did not exhibit clastogenic potential *in vivo* in the mouse micronucleus test. In rats, fertility and reproductive performance were not affected by cefixime at doses up to 25 times the adult therapeutic dose.

Ofloxacin

Preclinical effects in conventional studies of safety pharmacology, acute toxicity, repeated dose toxicity, reproductive studies were observed only at exposures considered sufficiently in excess of the maximum human exposure, indicating little relevance to clinical use. Joint toxicity was observed at exposure in the human therapeutic range in juvenile rats and dogs. Ofloxacin exhibits a neurotoxic potential and causes reversible testicular alterations at high doses.

Mutagenicity studies showed no evidence for mutagenicity of ofloxacin. However, like some other quinolones Ofloxacin is phototoxic in animals at exposure in the human therapeutic range. The phototoxic, photomutagenic and photocarcinogenic potential of ofloxacin is comparable with that of other gyrase inhibitors.

Preclinical data from conventional genotoxicity studies reveal no special hazard to humans, but carcinogen potential has not been investigated.

Ofloxacin has no effect on fertility, peri- or postnatal development, and therapeutic doses did not lead to any teratogenic or other embryotoxic effects in animals. Ofloxacin crosses the placenta and levels reached in the amniotic fluid are about 30% of the maximal concentrations measured in maternal serum.

Description

OMNIX O Tablets are a formulation containing cefixime and ofloxacin.

Cefixime is a semisynthetic, cephalosporin antibacterial for oral administration. Chemically, it is (*6R,7R*)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-vinyl-5-thia-1-azabicyclo [4.2.0] oct-2-en--2-carboxylic acid, 72-(*Z*)-[*O*-(carboxy methyl) oxime] trihydrate.

Molecular weight = 507.50 as the trihydrate. Chemical formula is C16H15N5O7S2.3H2O

Ofloxacin is a synthetic, broad-spectrum antimicrobial agent for oral administration. Chemically, ofloxacin, a fluorinated carboxyquinolone, is the racemate, (±)-9-fluoro-2,3-dihydro-3-methl-10-(4-methyl-1-piperazinyl)-7-oxo-7*H*-pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid.

Pharmaceutical Particulars

Incompatibilities

Not applicable.

Shelf-Life

As on the pack.

Packaging Information

Each Strip contains 10 tablets

Storage and Handling Instructions

Store in a cool and dry place. Protect from Light. Keep out of reach of children

Patient Counselling Information

● What is OMNIX O Tablets and what it is used for?

OMNIX O Tablets contain two antibiotics called cefixime and ofloxacin.

Cefixime belongs to a group of antibiotics called ‘cephalosporins’. Cefixime is used to treat infections caused by bacteria.

Ofloxacin belong to a group of medicines called ‘quinolone antibiotics’. Ofloxacin is an antibiotic that can be used to treat a variety of different infections.

● Do not take if you have an allergy to this drug

Do not take **OMNIX O Tablets** if you are allergic to cefixime, ofloxacin or to any of the other ingredients in this medicine.

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.

Do not take this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **OMNIX O Tablets**.

● Before you take OMNIX O Tablets, tell your HCP about other medication.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because **OMNIX O Tablets** can affect the way some other medicines work. Also some medicines can affect the way **OMNIX O Tablets** work.

In particular, tell your doctor if you are taking the following:

• Medicines to thin the blood, such as warfarin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, (e.g. clomipramine, amitriptyline), some antimicrobials (that belong to the group of macrolides, e.g. erythromycin, clarithromycin, azithromycin), some antipsychotics used to treat mental health conditions such as schizophrenia and bipolar disorder.

Tell your doctor if you are taking any of the following medicines:

- Medicines or dietary supplements that contain iron (for anaemia) or zinc

- Sucralfate used for stomach ulcers

- Antacids used for indigestion that contain magnesium or aluminium.

  - This medicine should not be taken within 2 hours of taking iron or zinc tablets, antacids or sucralfate, as these medicines can stop ofloxacin from working properly.

  - Corticosteroids, used for treatment of inflammation and swelling or over-active immune system. These may increase the risk of you developing a tendon rupture

  - Painkillers called non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ibruprofen or diclofenac or theophylline, used to treat asthma or chronic obstructive pulmonary disease as these could make you more prone to fits if taken with ofloxacin

  - Glibenclamide, a medicine to control your blood sugar as the amount of these medicines in the blood may increase and have greater effect.

  - Drugs that may affect your kidney function, e.g. cimentidine, probenicid and methotrexate as they can increase the level of ofloxacin in the blood.

  - Medicines to thin your blood, e.g. warfarin. Taking these with ofloxacin can increase the time it takes for your blood to clot.

  - If you are taking didanose chewable or buffered tablets (a medicine used to treat HIV infections), you should not take them 2 hours before or after this medicine.

- Water tablets (diuretics) such as furosemide

If you are due to have urine tests for porphyrin (a pigment in the blood), or for opiates (strong painkillers), tell your doctor or nurse you are taking this medicine.

● How to take OMNIX O Tablets

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

• Take this medicine by mouth

• If you feel the effect of the medicine is too weak or too strong, do not change the dose yourself, but ask your doctor. Carefully read the label from the pharmacist. Ask your pharmacist if you are not sure about the dose to take. The medicine should be taken for the prescribed number of days.

If you take more OMNIX O Tablets than you should: If you have too much of this medicine, talk to your doctor straight away. **If you forget to take OMNIX O Tablets** If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking OMNIX O Tablets: Do not stop taking this medicine without talking to your doctor. You should not stop taking **OMNIX O Tablets** just because you feel better. This is because the infection may come back or get worse again

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

● What are the possible side effects?

Cefixime

Like all medicines, this medicine can cause side effects although not everybody gets them.

Tell your doctor straightaway or go to the nearest hospital casualty department if you notice any of the following serious side effects – you may need urgent medical treatment:

• You have an allergic reaction. The signs may include a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

• Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also, flu-like symptoms and fever. This may be something called ‘Stevens-Johnsonsyndrome’.

• Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also, a feeling of being generally unwell, fever, chills and aching muscles. This may be something called ‘toxic epidermal necrolysis’.

• You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called ‘erythema multiforme’.

• You get infections more easily than usual. This could be because of a blood disorder. This normally gets better after stopping the medicine. You bruise or bleed more easily than normal. This could be because of a blood disorder. This normally gets better after stopping the medicine.

• If your child gets nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), shortness of breath. This may be due to haemolytic anaemia.

• Changes in the way the kidneys are working or blood in your child's urine.

• Fits (convulsions) – frequency not known.

• A brain condition with symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. This may be something called 'encephalopathy'. This side effect is more likely if you have taken an overdose or you already have a problem with your kidneys.

Stop taking this medicine and contact your doctor without delay if you get

• severe watery diarrhoea that will not stop and you are feeling weak and have a fever. This may be something called 'Pseudomembranous colitis'

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

• Feeling sick (nausea) or being sick (vomiting)

• Stomach pains, indigestion or wind

• Headaches

• Feeling dizzy

• Feeling itchy in the genital or vaginal area

Tell your doctor if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

Blood tests

OMNIX O Tablets can cause blood clots or small changes to the way the liver and kidney work. This would be shown up in blood tests. This is not common and goes back to normal after stopping this medicine.

Reporting of side effects

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

Ofloxacin

Like all medicines, this medicine can cause side effects although not everybody gets them. Stop taking ofloxacin and tell your doctor or go to your nearest hospital casualty department straight away if you have any of the following serious side effects, you may need medical attention:

Uncommon (may affect up to 1 in 100 people)

· Resistance of infection-causing organisms to this treatment, (you may fail to respond to treatment).

Rare (may affect up to 1 in 1,000 people)

· You may have an allergic reaction. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction), with symptoms such as the following:

  - Severe skin rash
  - Swelling of the face, lips, mouth, tongue or throat (angio-oedema)
  - Anaphylactic shock (sudden wheezing, swelling of your lips, tongue and throat or
  - body, rash, fainting or difficulties in swallowing)

· Inflammation of the bowel, which may cause severe watery diarrhoea, which may have blood in it, possibly with stomach cramps and a high temperature.

· Swelling of the tendons with the following symptoms: pain, tenderness, sometimes restricted movement (tendonitis). This can lead to tendon rupture, especially of the large tendon at the back of the ankle (Achilles' tendon). The risk of this occurring is increased if you are also taking corticosteroids, e.g. prednisolone.

· Numbness or tingling in the hands and feet or being very sensitive to touch, numbness or weakness of the arms and legs.

· Blurred, double or altered colour vision. If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.

Very rare (may affect up to 1 in 10,000 people)

· A condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal or due to an illness resulting from the destruction of red blood cells, with the following symptoms: feeling tired, faint, dizzy, being short of breath when exercising and having pale skin. These may be signs of anaemia or haemolytic anaemia.

· Other blood disorders when the number of different types of cells in the blood may reduce, which may cause fever, chills, sore throat, ulcers in the mouth and throat (leucopaenia, agranulocytosis).

· Fits (seizures).

· Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme).

· A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis).

· Narrowing, blockage or leakage of blood vessels, leading to (in exceptional cases) severe skin reactions and death of areas of the skin.

· Severe kidney problems, which may result in your kidneys stopping working. Signs may include a rash, high temperature, general aches and pains, or blood in the urine.

· Hearing problems or hearing loss.

· Liver problems, such as inflammation of the liver (hepatitis) or blockage in the bile duct, which may cause your eyes or skin to go yellow (jaundice), or you may notice the following

symptoms: nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, light-coloured bowel motions, dark-coloured urine.

Not known (frequency cannot be estimated from the available data)

· Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart).

· Severe depression or mental illness. Some people who are depressed think of harming or killing themselves.

· A serious reduction in all types of blood cells (pancytopaenia), which may result from a failure of the bone marrow to produce these cells.

· Widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

· Swelling of the lungs with the following symptoms; coughing, difficulty breathing, wheezing.

· Temporary paralysis or weakness of the muscles (rhabdomyolysis), disease of the muscles with the following symptoms: aching muscles, muscle tenderness or weakness, not caused by exercise.

· An attack of porphyria (a rare blood pigment disorder) in patients with this disease.

· Muscle or ligament rupture.

· Inflammation of the pancreas (pancreatitis) – you may have severe pain in the stomach and back.

· Loss of consciousness (coma), due to severe reduction in blood sugar levels

· Inflammation of the eye (uveitis)

· Skin redness with excessive scaling (exfoliative dermatitis).

· Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen). These may be signs of liver problems, which may include a fatal failure of the liver.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

Uncommon (may affect up to 1 in 100 people)

· Feeling sick (nausea) or being sick (vomiting), diarrhoea or stomach pains

· Irritated or burning eyes

· Headaches, sleep disturbances, including difficulty sleeping (insomnia)

· Feeling dizzy, having spinning sensations

· Agitation, feeling restless

· Cough and inflamed sore nose or throat (nasopharyngitis)

· Fungal infection

· Skin rash or itching

Rare (may affect up to 1 in 1,000 people)

· Loss of appetite

· Fast heart beat

· Drowsiness

· Feeling confused or anxious, nightmares, seeing, feeling or hearing things that are not there, depression and mental illness.

· Changes in or loss of your sense of taste or smell

· Shortness of breath or wheezing

· Changes in levels of liver enzymes or bilirubin, which may be seen in blood tests

· Excessive sweating and hot flushes

· Changes in kidney function shown in blood tests

· Feeling faint, lightheaded or dizzy, which may be due to low blood pressure

· Hives (urticaria)

· Rash with pimples

Very rare (may affect up to 1 in 10,000 people)

· Uncontrolled movements, unsteadiness and shaking

· Unusual bleeding or bruise more easily than normal (thrombocytopaenia)

· Increase in some white blood cells (eosinophilia)

· Ringing in the ears (tinnitus)

· Joint and muscle pains

· Skin rashes or eruptions, which may be caused by strong sunlight.

· Unusual purple discolouration under the skin, which may be due to bleeding or bruising due to leaky or damaged blood vessels

Not known (frequency cannot be estimated from the available data)

· A red, scaly rash with bumps under the skin and blisters (exanthemous pustolosis).

· Muscular weakness

· Feeling weak or irritable, sweating and/or trembling. This could be due to lowering of blood sugar (glucose) levels especially in patients with diabetes or existing low blood sugar.

· An increase in blood sugar levels

· Feeling of nervousness, tremor, unusual (involuntary) muscle movements

· Fainting

· Digestive problems such as stomach upset (indigestion/heartburn), constipation, or wind.

· General pain, pains in your muscles and stiffness in the bones/joints (arthritis), feeling unwell (asthenia), or fever.

● How should I store OMNIX O Tablets?

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (which is stated on the label and blister pack after EXP:). Store below 25°C.

Do not throw away 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.

● General information about the safe and effective use of this drug.

Talk to your doctor or pharmacist before taking OMNIX O Tablets

- if you have ever had colitis

- if you have kidney problems

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine can cause symptoms including fits (convulsions), feeling confused, feeling less alert or aware of things than usual, unusual muscle movements or stiffness. If you experience any of these effects don’t drive or use machinery.

Medical tests

If you require any tests (such as blood or urine tests) while taking **OMNIX O Tablets**, please make sure your doctor knows that you are taking this medicine.

● Any other information

Not applicable.

Details of the Manufacturer

Malik Lifesciences Pvt. Ltd. (A Subsidiary of Akums Drugs & Pharmaceuticals Ltd.).Plot No.-16,Vardhman Indl.Estate,N.H.58,

Haridwar-247667, (Uttarakhand).

Details of Permission or Licence Number with Date

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