Size: 3.5 x 6 Inch

OFZOLE

Ofloxacin 200 mg and Ornidazole 500 mg Tablets

Prescription only Medicines

Composition

Each film coated tablet contains

Ofloxacin BP	200 mg
Ornidazole	500 mg
Excipients	Q.S.

Colour: Tartrazine

Pharmacological properties

Pharmacodynamics properties

Ofloxacin

It is active after oral administration. It inhibits bacterial DNA replication by blocking DNA topo-isomerases, in particular DNA gyrase. Therapeutic doses of ofloxacin are devoid of pharmacological effects on the voluntary or autonomic nervous systems.

Ornidazole

After passive absorption into bacterium cell, the nitro group of ornidazole is reduced to amine group by ferrodoxin type redox system. The formation of redox intermediate intracellular metabolites is believed to be the key component of microorganism killing for Ornidazole. The mechanism of action is similar in protozoa.

Microbiology

Microbiological results indicate that the following pathogens may be regarded as sensitive: Staphylococcus aureus (including methicillin resistant staphylococci), Staphylococcus epidermidis, Neisseria species, Escherichia coli, Citrobacter, Klebsiella, Enterobacter, Hafnia, Proteus (indolenegative and indole-positive strains), Haemophilus influenza, Chlamydiae, Legionella, Gardnerella. Variable sensitivity is shown by Streptococci, Serratia marcescens, Pseudomonas aeruginosa and Mycoplasmas. Anaerobic bacteria (e.g. Fusobacterium species, Bacteroides species, Eubacterium species, Peptococci, Peptostreptococci) are normally resistant. Ofloxacin is not active against Treponema palladium.

Pharmacokinetic properties

Ofloxacin

Ofloxacin is almost completely absorbed after oral administration. Maximal blood levels occur 1-3 hours after dosing and the elimination half-life is 4-6 hours. Ofloxacin is primarily excreted unchanged in the urine. In renal insufficiency the dose should be reduced.

Ornidazole

Ornidazole is readily absorbed from the GIT and peak plasma concentrations of about 30 mcg/ml are achieved within 2 hours of a single dose of 1.5 g. Food does not affect extent but rate of absorption of ornidazole. Ornidazole is less than 15% bound to plasma proteins. It is widely distributed in body tissues and fluids, including cerebrospinal fluid. Antibacterial concentrations are achieved in vaginal secretions, amniotic fluid, appendix and intestinal tissues. More than 90% of ornidazole dose is metabolized in liver. The metabolites are active and have same activity against anaerobic bacteria as the ornidazole. The elimination half-life (t1/2) of ornidazole is 12-14 hours. It is excreted in the urine, mainly as conjugates and metabolites and to a lesser extent in the feces. Biliary excretion may be important in the elimination of ornidazole and its metabolites.

Rationale for combination of ofloxacin and ornidazole

Few studies have shown the combination of Nitroimidazoles and Quinolones to be effective clinically. This gives an indication for combining ornidazole and ofloxacin especially in mixed infections. Ornidazole which is a new derivative of Nitroimidazoles series has a longer half-life. It is recommended to be given twice a day. Ofloxacin is also recommended twice daily. Therefore, it appears appropriate to combine ornidazole and ofloxacin as fixed dose combinations. Moreover, FDC will provide broad spectrum of activity as individual drugs are active against both aerobic and anaerobic infection.

Indications

OFZOLE is indicated for empirical treatment of mixed aerobic-anaerobic infections commonly seen in clinical practice e.g. intra-abdominal infection, gynaecological and pelvic infections, foot ulcers especially in diabetes, lung abscess, infections in immuno-compromised patients etc.

Posology and method of administration

Route of administration: Oral

One tablet is recommended as twice daily therapy.

Contraindications

Ofloxacin should not be used in patients with known hypersensitivity to 4-quinolone antibacterials or any of the tablet excipients.

Ofloxacin should not be used in patients with a past history of tendinitis.

Ofloxacin, like other 4-quinolones, is contra-indicated in patients with a history of epilepsy or with a lowered seizure threshold.

Ofloxacin is contraindicated in children or growing adolescents, and in pregnant or breast-feeding women, since animal experiments do not entirely exclude the risk of damage to the cartilage of joints in the growing subject.

Patients with latent or actual defects in glucose-6-phosphate dehydrogenase activity may be prone to haemolytic reactions when treated with quinolone antibacterial agents.

Patients with known hypersensitivity to ornidazole or any component of this formulation or active renal disease or hepatic cirrhosis.

Warnings and precautions for use

Ofloxacin: Patients being treated with ofloxacin should not expose themselves unnecessarily to strong sunlight and should avoid UV rays. Caution is recommended if the drug is to be used in psychotic patients or in patients with a history of psychiatric disease.

Administration of antibiotics, especially of prolonged, may lead to proliferation of resistant micro-organisms. The patient's condition must therefore be checked at regular intervals. If a secondary infection occurs, appropriate measures must be taken.

Ornidazole: Regular laboratory tests and clinical control are indicated in case of use of high ornidazole doses or if duration of therapy exceeds 10 days. Blood disorders: Leukocyte counts should be checked before and after start of therapy (especially in repeat therapy), in patients with history of blood disorders. CNS: Severe diseases of central and peripheral nervous system may get aggravated on ornidazole therapy. Treatment should be discontinued in case of onset of peripheral neuropathy, ataxia, vertigo or confusion. Candidiasis: Ornidazole therapy may aggravate existing candidiasis. Necessary precautions should be taken.

Drug interactions

Ofloxacin: Co-administered magnesium/aluminium antacids, sucralfate or iron preparations can reduce absorption. Therefore, ofloxacin should be taken 2 hours before such preparations. Prolongation of bleeding time has been reported during concomitant administration of ofloxacin and anticoagulants. There may be a further lowering of the cerebral seizure threshold when quinolones are given concurrently with other drugs which lower the seizure threshold, e.g. Theophylline. However ofloxacin is not thought to cause a pharmacokinetic interaction with theophylline, unlike some other fluoroquinolones. Further lowering of the cerebral seizure threshold may also occur with certain nonsteroidal anti-inflammatory drugs. Ofloxacin may cause a slight increase in serum concentrations of glibenclamide administered concurrently; patients treated with this combination should be closely monitored. With high doses of quinolones, impairment of excretion and an increase in serum levels may occur when co-administered with other drugs that undergo renal tubular secretion (e.g. Probenecid, cimetidine, furosemide and methotrexate). Interaction with laboratory tests: Determination of opiates or porphyrins in urine may give false-positive results during treatment with ofloxacin.

Ornidazole: Alcohol intolerance: Unlike other nitro-imidazole, ornidazole does not inhibit enzyme aldehyde dehydrogenase. No disulfiram like reaction has been reported on consumption of alcohol. However, as is the case with all imidazole, this drug should be avoided in concomitance with alcohol usage. No clinically relevant interactions were seen with food and no interaction was found between ofloxacin and theophylline.

Pregnancy and lactation

No controlled studies of effect of the drug on pregnant women are available. Ornidazole should be prescribed to pregnant and nursing women only if the potential benefit to the mother outweighs potential risk to the foetus/ neonate.

Lithium therapy: 5-nitroimidazoles (mainly metronidazole) have been found to decrease renal elimination of lithium. So, in patients undergoing concurrent lithium therapy , plasma lithium concentrations as well as creatinine and electrolyte concentrations should be monitored.

Ofzole should be used with caution in conditions where the individual drugs have been used with precautionary approach.

Side effects

Ofloxacin:

Nausea and vomiting, diarrhoea, abdominal pain, gastric symptoms, Headache, dizziness, sleep disorders, restlessness, Tachycardia, Disturbances of kidney function, Skin rash, itching, Malaise.

Ornidazole:

Gastrointestinal effects like nausea, vomiting, anorexia and metallic or bitter taste. CNS effects like dizziness, vertigo and somnolence, rigidity, tremor, coordination problems, convulsions (rare), impairment of consciousness and signs of sensitive or mixed peripheral neuropathy have been observed.

Blood dyscrasias like medullar aplasia and neutropenia may be encountered occasionally. Other adverse events such as fatigue, loose stools, headache and Skin rash, itching have also been reported.

Overdosage and its Treatment

The most important signs to be expected following acute overdosage are CNS symptoms such as confusion, dizziness, impairment of consciousness and convulsive seizures as well as gastrointestinal reactions such as nausea and mucosal erosions. In the case of overdose steps 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. Elimination of ofloxacin may be increased by forced diuresis. In case of overdosage, the patient should be observed carefully and symptomatic treatment should be given. The stomach should be emptied by gastric lavage or vomiting. All the supportive measures and hydration should be maintained. In case of convulsions, intravenous diazepam is recommended.

Storage condition

Store below 30 °C. Protect from light and moisture.

Keep out of reach and sight of children.

SHELF LIFE: 24 months

PRESENTATION: 1 Alu/Alu Blister of 10 Tablets in a printed carton with a pack insert.

I-CARE

Care and Concern

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