

CHANGE

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

Abbreviated Prescribing information for CHANGE (Ofloxacin 200mg and Ornidazole 500mg Tablets)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Ofloxacin is a quinolone-carboxylic acid derivative with a wide range of antibacterial activity against both gram negative and gram positive organisms. Ornidazole is an antiprotozoal and antibacterial agent.

INDICATION: For diarrhoea of mixed infection.

DOSAGE AND ADMINISTRATION: One tablet is recommended as twice daily therapy. Duration of treatment will depend upon on the severity of infection.

CONTRAINDICATION: Contraindicated in patients with a history of hypersensitivity associated with the use of ofloxacin or ornidazole or any member of the quinolone group or other nitroimidazole derivatives, history of tendonitis, history of epilepsy or with a lowered seizure threshold, children or growing adolescents, and in pregnant or breast-feeding women and latent or actual defects in glucose-6-phosphate dehydrogenase activity.

WARNINGS & PRECAUTIONS: Caution is advised in patients for *clostridium difficile*-associated disease, diseases of the CNS, cardiac disorders, psychotic disorder, impaired liver function, treated with vitamin K antagonists, myasthenia gravis, peripheral neuropathy, hypoglycaemia, glucose-6-phosphate-dehydrogenase deficiency, rare hereditary disorders and while drive or operate machinery.

DRUG INTERACTION: *Ofloxacin:* antacids, sucralfate, metal cations, multivitamins, cimetidine, cyclosporine, drugs metabolized by Cytochrome P450 enzymes, NSAIDs, probenecid, theophylline, warfarin and antidiabetic agents (e.g., insulin, glyburide/glibenclamide), Interaction with Laboratory or Diagnostic Testing. *Ornidazole:* coumarin-type oral anticoagulants and vecuronium bromide.

ADVERSE REACTIONS: Nausea, insomnia, headache, dizziness, diarrhea, vomiting, rash, pruritus, external genital pruritus in women, vaginitis, dysgeusia, abdominal pain and cramps, chest pain, decreased appetite, dry mouth, fatigue, flatulence, gastrointestinal distress, nervousness, pharyngitis, pruritus, fever, rash, sleep disorders, somnolence, trunk pain, vaginal discharge, visual disturbances and constipation. Tremor, rigidity, poor coordination, seizures, tiredness, vertigo, temporary loss of consciousness and signs of sensory or mixed peripheral neuropathy.

MARKETED BY:



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(Additional information is available on request)