

FLAVOSPAS-O

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

Abbreviated Prescribing information for Flavospas-O (Flavoxate Hydrochloride and Ofloxacin Tablets)

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

PHARMACOLOGICAL PROPERTIES: Flavoxate blocks intracellular cyclic AMP accumulation and calcium and inhibits bladder contractions induced by various agonists or by electrical stimulation and inhibits the frequency of bladder voiding contractions. Ofloxacin specifically inhibits bacterial DNA gyrase which is required for DNA replication, transcription, repair and recombination. Its inhibition leads to expansion and destabilisation of the bacterial DNA and hence to cell death.

DOSAGE AND ADMINISTRATION:

To be taken as directed by the physician..

CONTRAINDICATION: Patients with known hypersensitivity of any component of this product, Achalasia, Urinary retention, Glaucoma, Myasthenia gravis, with a past history of tendinitis related to fluoroquinolone administration, history of epilepsy or with a lowered seizure threshold, with latent or actual defects in glucose-6-phosphate dehydrogenase activity may be prone to haemolytic reactions when treated with quinolone antibacterial agents. Children or growing adolescents and pregnant or breast-feeding women, since reported animal experiments do not entirely exclude the risk of damage to the cartilage of joints in the growing subject..

WARNINGS & PRECAUTIONS: The use in children below the age of <12 years is not recommended. Prescribers are advised to take into account the local prevalence of resistance in E. coli to fluoroquinolones. Due to increase in resistance to N. gonorrhoeae, ofloxacin should not be used as empirical treatment option in suspected gonococcal infection, unless the pathogen has been identified and confirmed as susceptible to ofloxacin. Caution should be taken when using fluoroquinolones, including ofloxacin, in patients with known risk factors for prolongation of the QT interval. 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.

DRUG INTERACTION: It can interact with Drugs known to prolong QT interval, Antacids, Sucralfate, Metal Cations, Theophylline, fenbufen or similar non-steroidal antiinflammatory drugs, Glibenclamide, Probenecid, cimetidine, furosemide and methotrexate and Vitamin K antagonists.

ADVERSE REACTIONS: Fungal infection, Pathogen resistance, Agranulocytosis, Bone marrow failure, Hypersensitivity, Hypoglycaemia in diabetics treated with hypoglycaemic agents, Hyperglycaemia, Hypoglycaemic coma, Agitation, Sleep disorder, Insomnia, Psychotic disorder and depression with self-endangering behaviour including suicidal ideation or suicide attempt, Nervousness, Dizziness, Headache, Somnolence, Tremor, Dyskinesia, Ageusia, Syncope, Benign intracranial hypertension (Pseudotumor cerebri), Eye irritation, Visual impairment, Uveitis, Glaucoma, Vertigo, Hearing impaired, Ventricular arrhythmias, torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged, Palpitations, Cough, Nasopharyngitis, Allergic pneumonitis, Severe dyspnea, Abdominal pain, Dry mouth, Diarrhea, Vomiting, Dyspepsia, Flatulence, Constipation, Pancreatitis, Jaundice, Hepatitis, which may be severe; Severe liver injury, including cases of acute liver failure, sometimes fatal, have been reported primarily in patients with underlying

liver disorders, Pruritus, Rash, Stevens-Johnson syndrome, Acute generalized exanthemous pustulosis; drug rash Stomatitis, Exfoliative dermatitis, Rhabdomyolysis and/or Myopathy, Muscular weakness, Muscle tear, muscle rupture, Ligament rupture, Arthritis, Acute interstitial nephritis, Attacks of porphyria in patients with porphyria and Asthenia Pyrexia Pain (including pain in the back, chest and extremities).

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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(Additional information is available on request)