8024396-9093

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

BALORAIN

(Balofloxacin Tablets 100 mg)

COMPOSITION

Each film coated tablet contains :

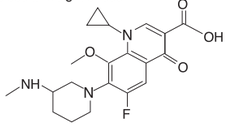
Balofloxacin 100 mg

Excipients q.s.

Colours : Lake of Quinoline Yellow & Titanium Dioxide I.P.

DESCRIPTION

Balofloxacin, a fluoroquinolone antibiotic with broad-spectrum activity against key respiratory pathogens for the treatment of community-acquired pneumonia, acute exacerbations of chronic bronchitis and acute sinusitis. It has excellent activity against *Streptococcus pneumoniae.* Balofloxacin is a white, crystalline powder. It is chemically designated as 1-Cyclopropyl-6-fluoro-8 methoxy-7-[3-(methylamino)piperdin-1-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylicacid. Its empirical formula $C_{20}H_{24}FN_3O_4$ and a molecular weight of 389.42.



DOSAGE FORM

Tablet

INDICATIONS

Balofloxacin is indicated for the treatment of uncomplicated urinary tract infection (such as cystitis, urethritis)

DOSAGE AND ADMINISTRATION

Balofloxacin is administered as the oral dosage of 100mg twice daily. Balofloxacin the dose and frequency should be adjusted to suit an individual patient's needs. For all patients the appropriate dosing regimen should be based upon individual response to treatment.

CONTRAINDICATIONS

Balofloxacin is contraindicated in patients with a history of hypersensitivity to this product, pregnant women and nursing mothers, Children and infants, Patients with a history of hypersensitivity, tendonitis and tendon rupture to quinolones.

PRECAUTIONS

Care should be taken in the patients with severe renal failure, patients with a history of spasmodic disease such as epilepsy, patients with a history of hypersensitivity to new-quinolones and the aged. Shock symptoms may occur rarely. If symptoms occur therapy should be discontinued and appropriate treatment initiate. Hypersensitivity reactions such as rash, urticaria, erythema, face edema and pruritis may occur infrequently. In such a case therapy should be discontinued. Renal function failures such as BUN and creatinine increase may occur infrequently. Elevations in SGOT, SGPT, LDH and ALP level may occur rarely and jaundice may occur rarely. If symptoms occur therapy should be discontinued and appropriate treatment to be initiated. Anemia, leukopenia, thrombocytopenia and eosinophilia may occur infrequently. In such a case therapy should be discontinued. Anorexia, abdominal pain, diarrhoea, nausea, constipation, disesthesia of abdomen and stomach, enlarged feeling of abdomen, indigestion, vomiting, thirst may occur infrequently. Colitis such as pseudomembranous colitis with hematocezia after other quinolones dosing were reported. If abdominal pain and frequent diarrhoea occur therapy should be discontinued and appropriate treatment initiate. Dizziness, infrequently headache, insomnia, infrequently fever and palpitation may occur. Hyperglycemia after other quinolones dosing were reported. (The aged, particulary patients of renal failure)

Teratogenicity

Balofloxacin was orally administered at doses of 3, 10, 30, 100, and 300 mg/kg/day to pregnant rats (Slc:SD) during the period of fetal organogenesis and effects of balofloxacin on the maternal reproduction, fetal and postnatal development were examined. General signs and bodyweights of dams did not change at any dosage groups, but decrease of food consumption and cecal distension were found in groups of 30 mg/kg/day and over. There were no treatment-related changes in the number of corpora lutea, implantation rate, and fetal mortality. Significant decreases in fetal bodyweights were found in male fetuses of 30, 100 and 300 mg/kg/day groups and in female fetuses of 300 mg/kg/day group. There were no significant differences in the incidences of external, visceral, and skeletal anomalies at any dosage groups. The incidence of skeletal variations increased at 300 mg/kg/day group, and especially the retardation of sternal ossification was frequently found. In addition, the number of ossified sacral and caudal vertebrae which indicate the progress of ossification significantly decreased at 100 and 300 mg/kg/day groups. Moreover, adverse effects were not exerted on the delivery, nurse of sucklings, physical and functional developments of postnatal offsprings at any dosage groups. Decrease of fetal bodyweights and/or retardation of fetal ossification were found in groups of 30 mg/kg/day and over, which suggests the growth retardation during fetal period. However, the retardation is regarded as slight and recoverable after birth. Therefore, although effects of balofloxacin on dams, such as decrease of food consumption, were found in groups of 30 mg/kg/day and over, the non-effective doses of balofloxacin are concluded to be 300mg/kg/day on the maternal reproduction and 10mg/kg/day on the fetal and postnatal development.

Balofloxacin was orally administered at doses of 2, 10 and 50 mg/kg/day to pregnant female Kbl:JW rabbits during the period of fetal organogenesis. Two out of 11 dams from the 10 mg/kg group and 2 out of 14 dams from the 50 mg/kg group died after administration period. Two dams from the 10 mg/kg group and 5 dams from the 50 mg/kg group aborted at late pregnant period. The dams before death or abortion showed a remarkable suppression of body weight and food intake. In dams from 10 and 50 mg/kg group, body weight and food intake were significantly decreased as compared with the control. By examination of the pregnant females on day 29 of pregnancy, fetal mortality was increased at the 10 and 50 mg/kg group and body weight of live fetuses and number of ossified sacral and caudal vertebrae were decreased at the 50 mg/kg group. But there were no treatment-related changes in the incidences of external, visceral, and skeletal abnormalities at any dosage level. These results indicated that a general toxicity in the maternal animals and increase of fetal mortality and suppression of fetal growth appeared following the 10 and 50 mg/kg dosing. The dose of balofloxacin without toxic effects on maternal reproduction and fetal development is concluded to be 2 mg/kg/day.

Balofloxacin was orally administered at doses of 10, 30, 100, and 300 mg/kg/day to female rats (Slc:SD) from day 17 of pregnancy to day 21 after delivery and effects of Q-35 on the maternal reproduction and postnatal development were examined. General signs and bodyweights of dams did not change at any dosage groups, but decrease of food consumption and cecal distension were found in groups of 100 mg/kg/day and over. Duration of gestation significantly extended at 300 mg/kg/day group. In addition, viability of neonates until 4 days age significantly decreased at 300 mg/kg/day group. However, treatment-related effects were not exerted on the physical and functional developments of offsprings after day 4 at any dosage groups. Although the general-toxicologically non-toxic dose of balofloxacin on dams is estimated at 30 mg/kg/day, the non-effective dose of balofloxacin on the maternal reproduction and postnatal development is concluded to be 100 mg/kg/day.

Fertility

Balofloxacin was orally administered at doses of 30, 100, and 300 mg/kg/day to male and female Slc:SD rats. The males from the 300 mg/kg/day group showed suppression of body weight gain. The males and females treated with 100 or 300 mg/kg/day and males treated with 30 mg/kg/day showed a transient decrease of food intake. Loose stool and increase of water intake in male and female were found in the 100 and 300 mg/kg/day groups. In 30, 100 and 300 mg/kg/day groups of males and females, cecal distension were observed. There were no effects on the estrus cycle, frequency of copulation, number of corpora lutea, implantation rate, fetal survival, fetal body weight, or external, visceral and skeletal morphology of fetuses in any dosage groups. The number of ossified sacral and caudal vertebrae which indicate the progress of ossification significantly decreased at 300 mg/kg/day. The dose of balofloxacin without toxic effect on parental reproduction is 300 mg/kg/day and on fetal development is 100 mg/kg/day .

DRUG INTERACTIONS

Administration of quinolones with antacids containing magnesium or aluminium interfere with the absorption of quinolones. The agent should not be taken at once. The concomitant administration of non-steroidal anti-inflammatory drug with quinolone may increase the risk of convulsive seizures. The concomitant administration of other quinolones with theophylline has elevated serum theophylline levels. Therefore the theophylline dosage should be decreased when quinolones are co-administred.

ADVERSE EFFECTS

The possible side effects are Nausea, Heartburn, Constipation, Dizziness, Fever, Indigestion, Urticaria, Diarrhoea, Thirst, Abdominal dysthesia, Pruritis, Palpitation, Abdominal pain, Headache, Anorexia.

CLINICAL PHARMACOLOGY

Pharmacodynamics: The bactericidal action of Balofloxacin results from interference with the enzyme DNA gyrase which is needed for the synthesis of bacterial DNA Balofloxacin is fluoroquinolone not only efficacious with Gram negative bacteria but also with enhanced activity against Gram positive bacteria, including MRSA and *Streptococcus pneumoniae.* Balofloxacin is more effective against bacteria, including *B.fragilis, P.gingvivalis, C.difficile, Peptostreptococci* known to be difficult to treat clinically.

Pharmacokinetics : The administration of oral doses of Balofloxacin to healthy volunteers, 50~400mg single oral dose and 200mg twice daily dose for 7 days produce no appreciable problems. Maximum serum concentrations are 1.0±0.2 μg/ml comparative high within 1 hour after dosing and the half-life of Balofloxacin is approximately 7 hours. Therefore it is estimated that twice dose of Balofloxacin a day is efficacious and also Balofloxacin is more effective against urinary tract infection because of 70~80% renal excretion.

STORAGE

Store below 25°C in a dry place. Protect from light.

Keep out of reach of children

PRESENTATION

Balorain is available as blister strip of 10 tablets.

torrent

Marketed by :

TORRENT PHARMACEUTICALS LTD.

Indrad-382 721, Dist. Mehsana, INDIA.

Manufactured by :

Hetero Labs Limited

Village : Kalyanpur, Chakkan Road, Baddi,

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