

TORFIX

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

Abbreviated Prescribing information for TORFIX [Rifaximin Tablets I.P.200 mg]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Rifaximin is an antibacterial agent of the rifamycin class that binds irreversibly to the beta sub-unit of the bacterial enzyme DNA-dependent RNA polymerase and consequently inhibits bacterial RNA synthesis. Rifaximin has a broad antimicrobial spectrum against most of the Gram positive and -negative, aerobic and anaerobic bacteria responsible for intestinal infections. Due to the very low absorption from the gastro-intestinal tract rifaximin in the polymorph α form is locally acting in the intestinal lumen and clinically not effective against invasive pathogens.

INDICATIONS: Torfix 200 indicated for the treatment of adult patients with infectious diarrhoea.

DOSAGE AND ADMINISTRATION: 200mg every 8 hours for three days (total 9 doses). Rifaximin must not be used for more than 3 days even if symptoms continue, and a second course of treatment must not be taken. Rifaximin can be administered with or without food.

CONTRAINDICATION: Hypersensitivity to rifaximin, rifamycin-derivatives or to any of the excipients. Cases of intestinal obstruction.

WARNINGS & PRECAUTIONS: Severe cutaneous adverse reactions (SCAR) including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported (frequency unknown) in association with rifaximin treatment. If the patient has developed a serious reaction such as SJS or TEN with the use of rifaximin, treatment with rifaximin must not be restarted in this patient at any time. Hepatic Impairment: use with caution in patients with severe (Child-Pugh C) hepatic impairment and in patients with MELD (Model for End-Stage Liver Disease) score > 25. Caution should be exercised when concomitant use of rifaximin and a P-glycoprotein such as ciclosporin is needed. Rifaximin 200 mg film-coated tablets are not recommended for use in children (<18 years old).

DRUG INTERACTIONS: In healthy subjects, clinical drug interaction studies demonstrated that rifaximin did not significantly affect the pharmacokinetics of CYP3A4 substrates, however, in hepatic impaired patients it cannot be excluded that rifaximin may decrease the exposure of concomitant CYP3A4 substrates administered (e.g. warfarin, antiepileptics, antiarrhythmics, oral contraceptives), due to the higher systemic exposure with respect to healthy subjects.

ADVERSE REACTIONS: Candidiasis, herpes simplex, nasopharyngitis upper respiratory tract infection, clostridial infections, lymphocytosis, monocytosis, neutropenia, thrombocytopenia, anaphylactic reactions, hypersensitivity, decreased appetite, dehydration, abnormal dreams, depressed mood, insomnia, nervousness, dizziness headache, hypoesthesia migraine paraesthesia sinus headache somnolence, presyncope, diplopia, ear pain, vertigo, palpitation, blood pressure increased, hot flush, cough, dry throat, dyspnoea, nasal congestion, oropharyngeal pain, rhinorrhea, abdominal pain, constipation, defecation urgency, diarrhoea, flatulence, abdominal distension, nausea, vomiting, rectal tenesmus, abdominal pain upper dry lips dyspepsia, gastrointestinal motility disorder faeces hard haematochezia mucous stools taste disorders, rashes, eruptions and exanthemas sunburn, stevens-johnson syndrome (SJS), toxic epidermal necrolysis (TEN), angioedema dermatitis, dermatitis exfoliative, eczema erythemas, pruritus purpura, urticarias, back pain muscle spasms muscular weakness myalgia neck pain, blood in urine glycosuria pollakiuria polyuria proteinuria, polymenorrhoea, asthenia conditions, chills, cold sweat, hyperhidrosis, influenza like illness, oedema peripheral, pain and discomfort, pyrexia, international normalized ratio abnormalities.

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(Additional information is available on request)