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.400/550 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 400 indicated for the treatment of hepatic encephalopathy. TORFIX 550 indicated for indicated for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years of age.

DOSAGE AND ADMINISTRATION: TORFIX 400 the recommended dose is one tablet every 8 hours orally. TORFIX 550mg the recommended dose is twice a day as long-term treatment. Orally with a glass of water.

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.

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: Anemia, ascites, nausea, abdominal pain upper, oedema peripheral, pyrexia, muscle spasms, arthralgia, dizziness, depression, dyspnoea, pruritus, rash, Clostridial infection, urinary tract infection, candidiasis, Pneumonia, cellulitis, upper respiratory tract infections, rhinitis, Thrombocytopenia, Anaphylactic reactions, angioedemas, hypersensitivity, anorexia, hyperkalemia, dehydration, confusional state, anxiety, hypersomnia, insomnia, headache, Balance disorders, amnesia, convulsion, attention disorders, hypoesthesia, memory impairment, hot flush, hypertension, hypotension, presyncope, syncope, pleural effusion, chronic obstructive pulmonary disease, abdominal distension, vomiting, oesophageal varices hemorrhage, dry mouth, stomach discomfort, constipation, liver function tests abnormality, Stevens-Johnson syndrome(SJS), Toxic epidermal necrolysis(TEN), Dermatitis, eczema, myalgia, back pain, Dysuria, pollakiuria, Proteinuria, Asthenia, International normalized ratio abnormalities, fall, Contusions, procedural pain.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/TORFIX/400,550mg/Feb-2026/02/ABPI

(Additional information is available on request)