

TORFIX 400/550

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

Abbreviated Prescribing information for TORFIX 400/550 (Rifaximin Tablets 400 mg/550 mg)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Rifaximin is an antibacterial drug of the rifamycin class that irreversibly binds the beta sub-unit of the bacterial enzyme DNA-dependent RNA polymerase and consequently inhibits bacterial RNA synthesis.

INDICATION: TORFIX 400: For the treatment of hepatic encephalopathy. TORFIX 550: For reduction in risk of Overt Hepatic Encephalopathy (HE) recurrence in patients \geq 18 years of age.

DOSAGE AND ADMINISTRATION: 400 mg thrice day or 550 mg twice a day with or without food with glass of water. Treatment beyond 6 months should take into consideration the individual balance between benefits and risks, including those associated with the progression of hepatic dysfunction.

CONTRAINDICATION: In patients with hypersensitivity to rifaximin, rifamycin-derivatives or to any of the excipients and in patients with intestinal obstruction.

WARNINGS & PRECAUTIONS: Risk of *Clostridium difficile* associated diarrhoea (CDAD), and reddish discolouration of the urine. Concomitant use with other rifamycins is not recommended due to potential for severe disruption of gut flora. Exercise caution when use in patients with hepatic impairment. As the effectiveness of oral oestrogenic contraceptives could decrease after rifaximin administration, take additional contraceptive precautions, in particular if the oestrogen content of oral contraceptives is less than 50 μ g.

DRUG INTERACTIONS: In hepatic impaired patients it cannot be excluded that rifaximin may decrease the exposure of concomitant CYP3A4 substrates administered (e.g. warfarin, antiepileptics, antiarrhythmics), due to the higher systemic exposure with respect to healthy subjects.

ADVERSE REACTIONS: Anaemia, ascites, nausea, abdominal pain upper, oedema peripheral, pyrexia, muscle spasms, arthralgia, dizziness, depression, dyspnoea, pruritus, rash, urinary tract infection, candidiasis, pneumonia, cellulitis, upper respiratory tract infections, rhinitis, thrombocytopenia, anorexia, hyperkalaemia, dehydration, confusional state, anxiety, hypersomnia, insomnia, headache, balance disorders amnesia, convulsion, attention disorders hypoesthesia, memory impairment, anaphylactic reactions, angioedemas, hypersensitivity, hot flush, hypertension, hypotension, presyncope, syncope, pleural effusion, chronic obstructive pulmonary disease, abdominal distension, diarrhoea, vomiting, oesophageal varices haemorrhage, dry mouth, stomach discomfort, constipation, liver function tests abnormalities, dermatitis, eczema, myalgia, back pain, dysuria, pollakiuria, proteinuria, oedema, pyrexia, asthenia, international normalised ratio abnormalities, fall, contusions and procedural pain .

MARKETED BY:



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(Additional information is available on request)