Xifaxan® is only available through Norgine in Germany. Not licensed in the UK

PRESCRIBING INFORMATION: XIFAXAN® (rifaximin)

Presentation: Blister pack for 12 film-coated tablets containing 200 mg rifaximin for oral administration.
Indication: Treatment of traveller's diarrhoea caused by non-invasive enteropathogenic bacteria in adults.
Dosage and administration: The recommended dose is 1 film-coated tablet (200 mg) every 8 hours. Dose can be increased to 2 film-coated tablets (400 mg) every 12 hours, if required. Maximum daily dose is 800 mg. Xifaxan can be taken with or without food orally. No experience in children. Dose adjustment not required for patients with liver or renal function disorder. Duration of treatment must not exceed 3 days.
Contraindications: Hypersensitivity to the active substance, other rifamycin derivatives or to any of the excipients.
Warnings and precautions: Should not be administered in patients with clinical signs of invasive enteritis, such as fever or bloody stool. Rifaximin can cause red coloration of urine. Pharmacokinetics of rifaximin have not been studied in patients with renal function disorder. Due to the fractional gastrointestinal absorption of rifaximin only an extremely marginal percentage is secreted from the urine (recovery rate following oral application: <0.3%). Patients with Crohn's disease, ulcerative colitis or other chronic-infectious gastric diseases should not take rifaximin.
Interactions: Rifaximin has little potential for systematic interactions with other medicinal products. No clinical interactions with medicinal products metabolized by cytochrome P450 isoenzymes are expected. Antibiotic treatment can change gut flora thus affecting the enterohepatic circulation of oestrogen, leading to decreased plasma concentration of oestrogen and thus affecting birth control. Use of additional contraceptives is recommended. Rifaximin should be taken at least 2 hours after administration of medical charcoal.
Pregnancy and lactation: Clinical data on the use of rifaximin in pregnancy is not available. It is not known whether rifaximin passes into the breastmilk.
Undesirable effects: Very common (>10%): flatulence. Common (> 1% and <10%): drowsiness, headache, abdominal tension, abdominal pain, constipation, rectal tenesmus, nausea, vomiting, prostration, pyrexia. Uncommon (>0.1% and <1.0%): herpes simplex, nasopharyngitis, pharyngitis, infections of upper airways, lymphocytosis, monocytosis, neutropenia, anorexia, dehydration, abnormal dreams, depressive mood, insomnia, nervousness, ageusia, hypoasthesia, migraine, sinus headache, somnolence, diplopia, earache, dizziness, hot flushes, cough, dry throat, dyspnea, congested nose, throat and larynx pain, rhinorrhea, upper abdominal pain, diarrhoea, dyspepsia, gastrointestinal motility disorders, dry lips, hematochezia, slimy stool, rash, cold sweat, blotchy skin rash, hyperhidrosis, back pain, muscle cramps, muscle weakness, myalgia, neck pain, glycosuria, pollakiuria, polyuria, proteinuria, polymenorrhea, asthenia, discomfort in the thoracic cavity, pain in the thoracic cavity, paraesthesia, flu-like illnesses, pain, shivers, sunburn, increased blood pressure, increased liver enzyme counts (aspartate-aminotransferase), blood in the urine.

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Prescribers should consult country approved prescribing information for further information in relation to undesirable effects.

Overdose: Gastric emptying and suitable supportive treatment is recommended.

Price and pack sizes: Germany: 12 x 200mg. Contact local distributor for price.

Legal category: Germany: POM.

Marketing authorisation holder: Norgine BV, Hogehilweg 7, 1101CA Amsterdam ZO, The Netherlands.

Product licence number: Germany: 57595.00.00

Date International Prescribing Information prepared: 17 September 2009

Company reference: INT/XIF/0909/0050

Xifaxan® has varying availability and licensing internationally. Before prescribing, consult your country approved prescribing information, available from your local distributor or Norgine Ltd.

Adverse events should be reported to your regulatory agency. Adverse events should also be reported to your local distributor or Norgine Limited, Chaplin House, Moorhall Road, Harefield, Uxbridge, Middlesex UB9 6NS, United Kingdom.