

When Travellers' Diarrhoea strikes...

...treat the cause
not just the symptoms.¹

The only virtually non-absorbed
antibiotic for the treatment of
non-invasive Travellers' Diarrhoea¹



Xifaxanta[®]

Rifaximin- α



XIFAXANTA[®] Prescribing Information

REFER TO FULL SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) BEFORE PRESCRIBING

Presentation: Film-coated tablet containing rifaximin 200 mg.
Uses: Xifaxanta is indicated for the treatment of travellers' diarrhoea that is not associated with fever, bloody diarrhoea, eight or more unformed stools in the previous 24 h, occult blood or leucocytes in the stool. **Dosage and administration:** Adults over 18 years of age: 200 mg every 8 hours for three days (total 9 doses). Rifaximin must not be used for more than 3 days even if symptoms continue or recur shortly after and a second course of treatment must not be taken. Not recommended in children under 18 years of age. No dose adjustment is necessary in elderly, hepatic or renal impairment, however, caution should be used in patients with impaired renal function. Rifaximin can be administered with or without food. **Contraindications:** Intestinal obstruction. Hypersensitivity to the active substance, to any rifamycin (e.g. rifampicin or rifabutin) or to any of the excipients. **Warnings and precautions for use:** Not recommended for the treatment of travellers' diarrhoea caused by invasive enteric pathogens. If symptoms worsen, treatment with rifaximin should be interrupted. The potential association of rifaximin treatment with *Clostridium difficile* associated diarrhoea and pseudomembranous colitis cannot be ruled out. Rifaximin

may cause a reddish discolouration of the urine. **Interactions:** Rifaximin may decrease the exposure of concomitantly administered CYP3A4 substrates (e.g. warfarin, antiepileptics, antiarrhythmics, oral contraceptives) in patients with hepatic impairment. Both decreases and increases in international normalized ratio (INR) have been reported in patients maintained on warfarin and prescribed rifaximin. If co-administration is necessary, the INR should be carefully monitored with the addition or withdrawal of rifaximin. Adjustments in the dose of oral anticoagulants may be necessary. Caution should be exercised with concomitant use of rifaximin and P-glycoprotein inhibitors such as ciclosporin. This may increase the systemic exposure of rifaximin. The clinical significance is unknown. Rifaximin should not be taken for at least 2 hours after the administration of charcoal. **Pregnancy and lactation:** As a precautionary measure, rifaximin is not recommended during pregnancy. The benefits of rifaximin treatment should be assessed against the need to continue breastfeeding. **Undesirable effects:** Common effects are dizziness, headache, abdominal pain, constipation, defecation urgency, diarrhoea, flatulence, abdominal distension, nausea, vomiting, rectal tenesmus and pyrexia. Other effects of unknown frequency that have been reported are: clostridial infections, thrombocytopenia, anaphylactic reactions, hypersensitivity, presyncope, liver function test abnormalities, skin reactions and INR abnormalities. **Licensing and legal category:** Legal category: POM. Cost: Basic

NHS price £15.15 (9 tablets), MA number: PL 20011/0021.

For further information contact: Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Middlesex, UB9 6NS. 01895 826606 E-mail: medinfo@norgine.com

Date of preparation: July 2017

Version number: UK/XIF2/0615/0031(3)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Medical Information at Norgine Pharmaceuticals Ltd on 01895 826606.

Reference:

1. Xifaxanta[®] Summary of Product Characteristics. Available from: <https://www.medicines.org.uk/emc/medicine/24974> [Accessed November 2017].

Product under licence from Alfasigma S.p.A. XIFAXANTA is a registered trademark of the Alfasigma group of companies, licensed to the Norgine group of companies. NORGINE and the sail logo are registered trademarks of the Norgine group of companies.



UK/XIF2/1117/0035

Date of preparation: November 2017.