
Specialist Initiated Drugs
Prescribing Information Sheet

January 2016

Rifaximin (Targaxan) for the treatment of Hepatic Encephalopathy

Formulary Status

Rifaximin for the treatment of hepatic encephalopathy should be initiated by a Consultant Gastroenterologist who will prescribe the initial supply in line with guidance in NICE TA 337.

The Gastroenterologist should continue to prescribe until the patient has been reviewed following at least one month of rifaximin. This will usually be between 4-8 weeks of treatment.

On-going prescribing can be continued by a GP.

The Specialist will review patients with HE at least every six months

The responsibility for monitoring and stopping treatment remains with the specialist. They should be consulted if a change in treatment is required.

Full prescribing guidance – Summary of Product Characteristics

<http://www.medicines.org.uk/emc/medicine/27427>

Indication and dosage

Indication: Rifaximin is indicated for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years of age

Presentation: Pink, film coated tablets containing 550mg rifaximin

Dosage and Administration: 1 x 550mg tablet should be taken TWICE a day with a glass of water. It may be taken with or without food.

Elderly: no dosage adjustment necessary.

Hepatic Impairment: no dosage adjustment necessary- see later/SPC

Renal Impairment: It is not anticipated that any adjustment should be needed (the drug is poorly absorbed).

Monitoring: (will be carried out by the Gastroenterologist)

- liver function tests- baseline, month one and every 6 months minimum
- HE symptoms- Westhaven grade every six months in clinic.
- Admissions for encephalopathy
- Improvement in neuropsychological function
- Improvement in quality of life

End of Treatment: if the patient shows no improvement in quality of life the rifaximin should be discontinued.

Approved by: East Kent Prescribing Group (Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)

Date: Jan 2016

Address: c/o Canterbury and Coastal CCG, Ground Floor, Council Offices, Military Road, Canterbury, Kent, CT1 1YW

Contact: T: 01227 791267 | E: accg.eastkentprescribing@nhs.net

Adverse effects, special warnings and precautions for use (consult SPC for full list)

Contra-indications: Hypersensitivity to rifaximin, rifamycin-derivatives or to any of the excipients; intestinal obstruction

Special warnings and precautions for use:

- *Clostridium difficile* associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including rifaximin. The potential association of rifaximin treatment with CDAD and pseudomembranous colitis (PMC) cannot be ruled out
- Combination with rifamycin antimicrobials: Due to the lack of data and the potential for severe disruption of gut flora with unknown consequences, concomitant administration of rifaximin with other rifamycins is not recommended.
- Urine discolouration: Patients should be informed that despite the negligible absorption of the drug (less than 1%), like all rifamycin derivatives, rifaximin may cause a reddish discolouration of the urine.
- 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
- Interaction with oral contraceptives: Due to the effects on the gut flora, the effectiveness of oral oestrogenic contraceptives could decrease after rifaximin administration. However, such interactions have not been commonly reported. It is recommended to take additional contraceptive precautions, in particular if the oestrogen content of oral contraceptives is less than 50 µg

Adverse effects:

- Rifaximin is generally well tolerated.
- Rifaximin may cause side effects of nausea, abdominal pain, dizziness, fatigue, headaches, muscle cramps and joint pain. It can also cause more serious side effects such as allergic reactions, rashes and itching.
- Rifaximin can alter the normal bacteria in the colon and encourage overgrowth of some bacteria such as *clostridium difficile* which causes inflammation of the colon (pseudomembranous colitis). Patients who develop signs of pseudomembranous colitis after starting rifaximin (diarrhoea, fever and abdominal pain) will be advised to contact their physician immediately.

Drug Interactions: Due to negligible gastrointestinal absorption of orally administered rifaximin (less than 1%), the systemic drug interaction potential is low. See above for oral contraceptives and SPC for further information.

Contact details of Specialist Team

- **Usually** via consultant secretary
- **Out of Hours:** Rifaximin may be stopped pending discussion with the consultant. In an emergency, if the GP has concerns about the patient's health, an admission may be required through the normal emergency channels. The on-call Gastroenterologist only deals with GI bleeds.
- **Specialist Nurse:** there is no specialist HE nurse

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