NHS
Telford and Wrekin
Clinical Commissioning Group

Prescribing information for rifaximin (Targaxan®▼) 550 mg tablets for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years

This prescribing information document outlines the prescribing responsibilities between the specialist and GP. GPs are invited to participate. If the GP feels that such prescribing is outside their area of expertise or has clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, clinical responsibility for the patient's health remains with the specialist.

If a specialist asks the GP to prescribe but the GP is not happy to continue prescribing, they must inform the specialist within 2 weeks of receiving the request.

Consultant details	GP details	Patient details
Name:	Name:	Name:
Address:	Address:	NHS Number:
Email:	Email:	Date of birth:
Contact number:	Contact number:	Contact:

Licensed Indication

Rifaximin 550mg tablets are indicated for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years of age.
The Summary of Product Characteristics (SPC) advises that in the pivotal study, 91% of the patients were using concomitant lactulose. Consideration should also be given to official guidance on the appropriate use of antibacterial agents.

Dosage and administration

The recommended dose is one 550mg tablet, twice a day. The clinical benefit was established from a controlled study in which subjects were treated for 6 months. Treatment beyond 6 months should take into consideration the individual balance between benefits and risks, including those associated with the progression of hepatic dysfunction. Rifaximin can be administered with or without food, and should be given with a glass of water.

Specialist responsibilities

- Initiation of rifaximin and follow-up to confirm there is an adequate response to treatment.
- Prescribe rifaximin for an initial period of one month and confirm adequate response before asking the GP whether he or she is willing to participate in continued prescribing.
- If the GP agrees to participate, discuss the arrangement with the patient.
- Discuss the benefits and side effects of treatment with the patient.
- Regular follow-up of patient.
- Communicate promptly with the GP when treatment is changed.
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
- Advise GP on dosage adjustment and when and how to stop treatment.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.
- Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Primary Care responsibilities

- Reply to the request for continued prescribing as soon as practicable within 2 weeks
- Prescribe rifaximin at the dose recommended.
- Adjust the dose as advised by the specialist.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Refer patient to the specialist if his or her condition deteriorates.
- Stop treatment on the advice of the specialist or initiate tapered withdrawal if advised to do so.
- Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Communication

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Hospital Pharmacy Dept:				
Other:				

Contra-indications, Special warnings/precautions & Adverse effects[1]

Contra-indications:

- Hypersensitivity to rifaximin, rifamycin-derivatives or to any of the product's excipients.
- Cases of intestinal obstruction

Special warnings/precautions:

- The potential association of rifaximin treatment with Clostridium difficile-associated disease and pseudomembranous colitis cannot be ruled out.
- Concomitant administration of rifaximin with other rifamycins is not recommended.
- Patients should be informed that despite the negligible absorption, in common with other rifamycins, 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.
- Whilst interactions have not been commonly reported, the use of additional contraceptive precautions is recommended, in particular if the oral contraceptive oestrogen content is below <50 micrograms.

Adverse Effects

Common adverse events (occurring in ≥1/100 to <1/10 of patients) as listed in the SPC: depression; dizziness; headache; dyspnoea; abdominal pain and distension; diarrhoea, nausea, vomiting, ascites, rashes, pruritus, muscle spasms, arthralgia, peripheral oedema. See SPC for full details of adverse events (www.medicines.org.uk) Rifaximin was launched in 2013 and has black triangle (▼) status. All suspected reactions (including those considered not to be serious and even where the causal link is uncertain) should be reported to the MHRA.

Drug Interactions

The SPC states that whilst studies in healthy subjects have shown no significant interaction, in hepatic impaired patients it cannot be excluded that rifaximin may decrease the exposure of concomitant CYP3A4 substrates administered (e.g. warfarin, antiepileptics, antiarrhythmics). An in vitro study has suggested that rifaximin is a moderate substrate of P-glycoprotein (P-gp) and is metabolized by CYP3A4. It is unknown whether concomitant drugs which inhibit P-gp and/or CYP3A4 can increase systemic exposure of rifaximin.

See product SPC for full list of drug interactions (www.medicines.org.uk)

This information is not inclusive of all prescribing information, potential adverse effects and drug interactions. Please refer to full prescribing data in the Summary of Product Characteristics (www.medicines.org.uk) or the British National Formulary (www.bnf.org).

[1] Rifaximin (Targaxan) 550mg Tablets – Summary of Product Characteristics. Available at www.medicines.org.uk