Rifaximin *(Targaxan®)*

SHARED CARE GUIDELINES:

FOR PRESCRIBING RIFAXIMIN (TARGAXAN®) ▼ FOR REDUCTION IN RECURRENCE OF EPISODES OF OVERT HEPATIC ENCEPHALOPATHY IN ADULT (≥ 18 YEARS OF AGE) PATIENTS

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways for managing the responsibilities for the prescribing of rifaximin for reduction in recurrence of episodes of overt hepatic encephalopthy in patients ≥ 18 years of age between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with hepatic encephalopathy are under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for rifaximin and the consequences of its use.

RESPONSIBILITIES and ROLES

	Specialist responsibilities
1	Assessment of the patient as a candidate for treatment with rifaximin in line with NICE guidance and local pathways for management of overt hepatic encephalopathy.
2	Consideration of any potential drug interactions of the intended treatment regimen with drugs that the patient may already be taking. See drug interactions section below for more details.
3	Initiate treatment and provide at least 28 days supply.
4	Discuss the benefits and side effects of treatment with the patient.
5	Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.
6	Inform the GP in writing of the patient's diagnosis, the treatment regimen to be used , start date of treatment, intended duration of treatment and management advice. Where appropriate the GP can be asked to take over the future prescribing of repeat treatment within this guidance.
7	Review the patient's condition and monitor response to treatment regularly where indicated. Changes to therapy as a result of these reviews (or at any other time) should be reported to the GP promptly.
8	Give advice to the GP on when to stop treatment.
9	Report adverse events to the MHRA (yellow card scheme) and share this information with the GP
10	Ensure that clear backup arrangements exist for GPs to obtain advice and support

	General Practitioner responsibilities
1	Referral of the patient to the specialist.
2	Reply to the request from the specialist to take on prescribing of this medication as soon as practicable.
3	Continue to prescribe the therapy requested, under the guidance of the specialist.
4	Monitor the patient at regular intervals in conjunction with specialist. Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
5	Consideration of any potential drug interactions of the intended treatment regimen with drugs that the patient may already be taking, or any newly-initiated drugs. See drug interactions section below for more details.
6	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
7	Stop treatment on the advice of the specialist.
8	Report adverse events to the specialist and MHRA (yellow card scheme).

Patient's role (or that of carer)
1 Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2 Share any concerns in relation to treatment with the medicine.
3 Report any adverse effects to the specialist or GP whilst taking the medicine.
4 If the patient is seen by another service, clinic or hospital, they should advise the healthcare professionals offering treatment about their treatment, particularly if new medicines are administered or prescribed.

BACK-UP ADVICE AND SUPPORT

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

SUPPORTING INFORMATION

Dosage and Administration
Recommended dose: 550 mg twice a day. Rifaximin should be taken orally with a glass of water, with or without food.

Duration of treatment
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. If treatment is to continue beyond 6 months the Specialist must give explicit advice on how to review ongoing treatment.

Contraindications to rifaximin treatment:

- Hypersensitivity to rifaximin, rifamycin-derivatives or to any of the excipients listed in the summary of product characteristics.
- Cases of intestinal obstruction.
- Patient aged <18 years.
- Patient is pregnant or breastfeeding.

Special considerations

- 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.
- 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.

Potential side effects
Side effects listed in the BNF (in order of frequency): nausea, vomiting, abdominal pain, flatulence, diarrhoea, dyspnoea, headache, depression, dizziness, muscle spasm, rash, pruritus; *less commonly:* anorexia, taste disturbances, dry mouth, peripheral oedema, sleep disturbances, anxiety, memory impairment, convulsions, hypoaesthesia, paraesthesia, antibiotic-associated colitis, influenza-like symptoms, dysuria, polyuria, glycosuria, polymenorrhoea, blood disorders, hyperkalaemia; rarely blood pressure changes, constipation; *also reported:* syncope
Interactions
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.
Due to the effects on the gut flora, the effectiveness of oral oestrogenic contraceptives could decrease after rifaximin administration. It is recommended to take additional contraceptive precautions, in particular if the oestrogen content of oral contraceptives is less than 50 µg.

The lists of potential side effects and potential drug interactions included within this document are not exhaustive. The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Drug costs (correct at March 2015, from BNF):
Targaxan® tablets, f/c, rifaximin 550mg, 56-tab pack = £259.23

References

Summary of Product Characteristics for Targaxan (Norgine Limited, accessed online 08/04/15)

NICE technology appraisal guidance 337: Rifaximin for preventing episodes of overt hepatic encephalopathy (issued March 2015)

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Document details
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