Targaxan 550 mg film-coated tablets (rifaximin-α).

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

Presentation:
Film-coated tablet containing rifaximin 550 mg.

Uses:
Targaxan is indicated for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years of age.

Dosage and administration:
Adults 18 years of age and over: 550 mg twice daily, with a glass of water, with or without food for up to 6 months.

Treatment beyond 6 months should be based on risk benefit balance including those associated with the progression of the patients hepatic dysfunction.

No dosage changes are necessary in the elderly or those with hepatic insufficiency. Use with caution in patients with renal impairment.

Contraindications:
Contraindicated in hypersensitivity to rifaximin, rifamycin-derivatives or to any of the excipients and in cases of intestinal obstruction.

Warnings and precautions for use:
The potential association of rifaximin treatment with *Clostridium difficile* associated diarrhoea and pseudomembranous colitis cannot be ruled out.

The administration of rifaximin with other rifamycins is not recommended.

Rifaximin may cause a reddish discolouration of the urine.

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.

In hepatic impaired patients, rifaximin may decrease the exposure of concomitantly administered CYP3A4 substrates (e.g. warfarin, antiepileptics, antiarrhythmics, oral contraceptives).

Both decreases and increases in international normalized ratio (in some cases with bleeding events) have been reported in patients maintained on warfarin and prescribed rifaximin. If co-administration is necessary, the international normalized ratio should be carefully monitored with the addition or withdrawal of treatment with rifaximin. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Ciclosporin may increase the rifaximin C_{max}

Pregnancy and lactation:
Rifaximin is not recommended during pregnancy.

The benefits of rifaximin treatment should be assessed against the need to continue breastfeeding.

Side effects:
Common effects reported in clinical trials are dizziness, headache, depression, dyspnoea, upper abdominal pain, abdominal distension, diarrhoea, nausea, vomiting, ascites, rashes, pruritus, muscle spasms, arthralgia and peripheral oedema.

Other effects that have been reported include:
Clostridial infections, urinary tract infections, candidiasis, pneumonia cellulitis, upper respiratory tract infection and rhinitis. Blood disorders (e.g. anaemia, thrombocytopenia). Anaphylactic reactions, angioedemas, hypersensitivity. Anorexia, hyperkalaemia and dehydration. Confusion, sleep disorders, balance disorders, convulsions, hypoesthesia, memory impairment and attention disorders. Hypotension, hypertension and fainting. Hot flushes. Breathing difficulty, pleural effusion, COPD. Gastrointestinal disorders and skin reactions. Liver function test abnormalities. Dysuria, pollakiuria and proteinuria. Oedema. Pyrexia. INR abnormalities.

Legal category: UK - POM, Ireland - Prescription only.

Cost: UK - Basic NHS price £259.23 for 56 tablets. Ireland - €262.41 for 56 tablets
Marketing Authorisation number: UK - PL 20011/0020. Ireland - PA 102/29/1

For further information contact:

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United Kingdom - 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.

Ireland - Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to Medical Information at Norgine Pharmaceuticals on +44 1895 826606.