Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
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NHS SCOTLAND

Product Update:

tacrolimus (as monohydrate) 0.75mg, 1mg and 4mg prolonged- release tablets (Envarsus®) SMC No. (1041/15)

Chiesi Ltd

6 March 2015

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

tacrolimus (Envarsus®) prolonged release-tablets are accepted for use within NHS Scotland.

Indication under review: Prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

Tacrolimus (Envarsus®) is suitable for use by patients for whom tacrolimus is an appropriate choice of immunosuppressive therapy. It has increased bioavailability compared with other tacrolimus preparations. Tacrolimus (Envarsus®) has demonstrated non-inferiority to a tacrolimus immediate-release capsule and has a similar cost per equivalent dose.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 05 February 2015.

Chairman, Scottish Medicines Consortium

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