

**AWMSG ADVICE PARTIALLY
SUPERSEDED BY
NICE GUIDANCE (TA481)
NICE GUIDANCE ISSUED OCTOBER 2017**

(Refer to NICE website for full guidance on NICE recommendations, including any specific restrictions on the use of the technology)

**Final Appraisal Recommendation
Advice No: 2315 – July 2015**

**Tacrolimus (Envarsus[®]) 0.75 mg, 1 mg, 4 mg
prolonged-release tablets**

Limited submission by Chiesi Ltd

Recommendation of AWMSG

Tacrolimus (Envarsus[®]) is recommended as an option for use within NHS Wales for the prophylaxis of transplant rejection in adult kidney or liver allograft recipients and the treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

Additional note(s):

- **The Medicines and Healthcare products Regulatory Agency and Commission on Human Medicines advise that oral tacrolimus products should be prescribed and dispensed by brand name only, to minimise the risk of inadvertent switching between products, which has been associated with reports of toxicity and graft rejection. Switching between tacrolimus brands requires careful supervision and therapeutic monitoring by an appropriate specialist.**

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2586, which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.



This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Chiesi Ltd
Date of first issue	July 2015
Last reviewed	May 2019

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All Wales Medicines Strategy Group. Final Appraisal Recommendation – 2315:
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