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Date: 7th October 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Envarsus 1mg modified release oral tablets (tacrolimus):
Interim Supply of United Kingdom Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Chiesi Ltd. is currently experiencing supply disruption with Envarsus 1mg modified release (tacrolimus) tablets in the UK.

To ensure continuity in supply of the above product, Chiesi UK has obtained approval from the MHRA to supply the UK with a batch of Envarsus 1mg modified release oral tablets (batch number 6505406A; 3000 packets of 30 tablets per packet) that has been packed with some foreign language information. This batch is expected to be on the UK market from mid-October 2020 to end of 2020.

Please note the following:

- This product is considered licensed in the UK.
- The product from Europe has the same formulation as the UK product
- The product from Europe is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are no differences between the European and UK product information. For this specific batch, the difference is that the blister pack and plastic pouch are printed using foreign languages. The carton and Patient Information Leaflet (PIL) remain unchanged and are printed in English
- Please refer to the UK approved PIL supplied with the packs.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/ or contact the company contact point (see below).
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Envarsus 1mg modified release (tacrolimus) tablets.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients

Call for reporting
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or wish more information about Envarsus 1mg Modified Release Tablets, please contact Chiesi UK Medical Information at Chiesi UK Ltd., 333 Styal Road, Manchester. M22 5LG or telephone +44 (0)161 488 5555 or medinfo.uk@chiesi.com

Signed, on behalf of Chiesi Ltd.

Shishir Patel

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