**Date: August 2023**

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Dailiport (tacrolimus) 3 mg prolonged-release hard capsules**
**Interim Supply of Belgium Stock to Mitigate Supply Disruption**

Dear Healthcare Professional / Homecare company / Wholesaler

## Summary: Sandoz is currently experiencing supply disruption with Dailiport 3 mg prolonged-release hard capsules in the UK.

To ensure continuity in supply, Sandoz has obtained approval from the MHRA to supply Belgium product (batch number MP7815), which is expected to be on the UK market from end of August to end of December 2023.

**Please note the following:**

- **This product is considered licensed in the UK.**
- **The product from Belgium has the same formulation as the UK product**
- **The product from Belgium is manufactured according to the same manufacturing process and quality controls as the UK product.**
- **There is a current interruption in the UK supply of Dailiport (tacrolimus) 3mg prolonged-release hard capsules, due to a manufacturing issue at Sandoz.**
- **To resolve this temporary issue a number of Dailiport 3mg packs originally destined for Belgium (batch number and expiry date shown below), have been repurposed for the UK.**
- **The only difference between the UK and Belgium product is the packaging (this includes the outer box, blister pack, aluminium bag and Patient Information Leaflet).**
- **Please refer to the UK approved PIL supplied with the Belgium packs. Discard the Belgium leaflet in the pack.**
- **For additional copies of the leaflet, please refer to https://products.mhra.gov.uk/ or contact the company contact point (see below).**
- **If a patient or caregiver contacts you with concerns about different packaging for Dailiport 3mg prolonged-release hard capsules, carefully check the differences and the batch numbers and expiry dates below, and if they match, please reassure patients that this product is the same as their usual UK product. If the numbers do not match, please follow your medicines falsification protocol.**
- **The MHRA has approved this product under a batch specific variation to the marketing authorisation.**

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

**Background**

There is a current interruption in the UK supply of Dailiport 3mg prolonged-release hard capsules, due to a manufacturing issue at Sandoz. This interruption is temporary with re-supply of UK stock anticipated for w/c 25 September 2023.

The MHRA have agreed that a limited number of Dailiport 3mg packs originally produced for use in Belgium can be repurposed for use in the UK. The only difference between the UK and Belgian product is the packaging (this includes the outer box, blister pack, aluminium bag and Patient Information Leaflet).

To ensure the correct Patient Information Leaflet (PIL) is available for UK patients, the Belgian packs are individually placed in clear plastic bags with a UK PIL and a copy of this letter inserted. This letter is intended to provide you with information to answer any questions and must be removed from the bag before it is given to the patient. The plastic bag will also contain a letter intended for patients to explain the difference in packaging.

**The batch numbers and expiry dates of the Belgian packs are as follows:**

| **Product Strength** | **Batch Number(s)** | **Expiry** |
|---|---|---|
| Dailiport 3mg prolonged-release hard capsules | MP7815 | 30 June 2024 |

The MHRA has agreed that Sandoz make Wholesale companies, Homecare companies and Hospital Pharmacies who are likely to dispense the product aware of this in case a patient or carer is concerned by this difference.

If a patient or caregiver contacts you with concerns about seeing different packaging for Dailiport 3mg hard capsules, carefully check the differences and the batch numbers and expiry dates above, and if they match, please reassure patients that this product is the same as their usual UK product.

If you require additional copies of this letter, please contact Sandozgb@EU.propharmagroup.com.

**Call for reporting**

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Adverse events should also be reported to Sandoz via adverse.event.uk@sandoz.com or online through the pharmacovigilance intake (PVI) tool at https://pvi1j.solutions.iqvia.com

If you have a question about the product, please contact Medical Information on 01276 698101 or via email at Sandozgb@EU.propharmagroup.com

***Company contact points***

If you have any questions, or if you require any further information, please contact the Sandoz Medical Information Team e-mail*:* Sandozgb@EU.propharmagroup.com Tel: +44 (0)1276 698 101

Yours faithfully,

Hannah Stevenson

Sandoz UK,

Interim Medical Director

UK | August 2023 | 295704