SANDOZ

Date: April 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Adoport (tacrolimus) 0.75mg hard capsules
Interim Supply of Nordic Stock

Dear Healthcare Professional / Homecare company / Wholesaler

Summary: Sandoz is currently experiencing supply constraints with Adoport (tacrolimus) 0.75mg hard capsules

To ensure continuity in supply, Sandoz has obtained approval from the MHRA to supply the Nordic product (Batch Number NG7762) which is expected to be on the UK market from April 2024.

Please note the following:

- **There is a current interruption in the UK supply of Adoport (tacrolimus) 0.75mg hard capsules due to manufacturing constraints at Sandoz.**
- **To resolve this temporary issue a number of Adoport 0.75mg packs originally destined for the Nordic countries of Sweden, Finland and Norway (batch number and expiry date shown below), have been repurposed for the UK.**
- **The only difference between the UK and the Nordic product is the packaging (this includes the outer box, bag, foil and Patient Information Leaflet).**
- **The Nordic product is considered licensed in UK.**
- **The Nordic product has the same formulation as the UK product.**
- **The Nordic product is manufactured according to the same manufacturing process and quality controls as the UK product.**
- **The Leaflet from the Nordic product can be discarded by the Patient**
- **Please refer Patients to the Patient Letter and UK Patient Information Leaflet (PIL) supplied with the Nordic packs.**
- **If a patient or caregiver contacts you with concerns about different packaging for Adoport 0.75mg, 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.**

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

Background

There is a current interruption in the UK supply of Adoport 0.75mg capsules, due to a manufacturing constraint at Sandoz. This interruption is temporary with re-supply of UK stock anticipated in next few months.

The MHRA have agreed that a number of Adoport 0.75mg packs originally produced for use in the Nordic countries can be repurposed for use in the UK. The only difference between the UK and the Nordic product is the packaging (this includes the outer box, foil and Patient Information Leaflet).

To ensure the correct Patient Information Leaflet (PIL) is available for UK patients, the Nordic packs are individually placed in clear plastic bags with a UK PIL and Patient Letter inserted. The letter is intended for patients to explain the difference in packaging of this batch.

The batch number and expiry date of the Nordics packs are as follows:

Product Strength	**Batch Number**	**Expiry**
Adoport (tacrolimus) 0.75mg hard capsules	NG7762	30-June-2025

The MHRA has agreed that Sandoz make Homecare companies and Wholesale Companies, who are likely to dispense the product aware of this in case a patient or carer is concerned by this difference. We will also notify the NHS Commercial Medicines Unit and share a copy of this letter with them via email for distribution.

If a patient or caregiver contacts you with concerns about seeing different packaging for Adoport 0.75mg packs, carefully check the differences and the batch number and expiry date above, and if they match, please reassure patients that this product is the same as their usual GB 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

Company contact points

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

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,

Medical Director