Sandoz Limited.
Park View,
Riverside Way,
Watchmoor Park,
Camberley,
Surrey,
GU15 3YL

Date: 08th June 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Adoport (tacrolimus) 2 mg capsules:
Interim Supply of Italian Stock to Mitigate Supply Disruption

Dear Healthcare Professional/ Homecare company/ Wholesaler,

Summary: Sandoz Limited is currently experiencing supply disruption with Adoport (tacrolimus) 2 mg capsules in the UK.

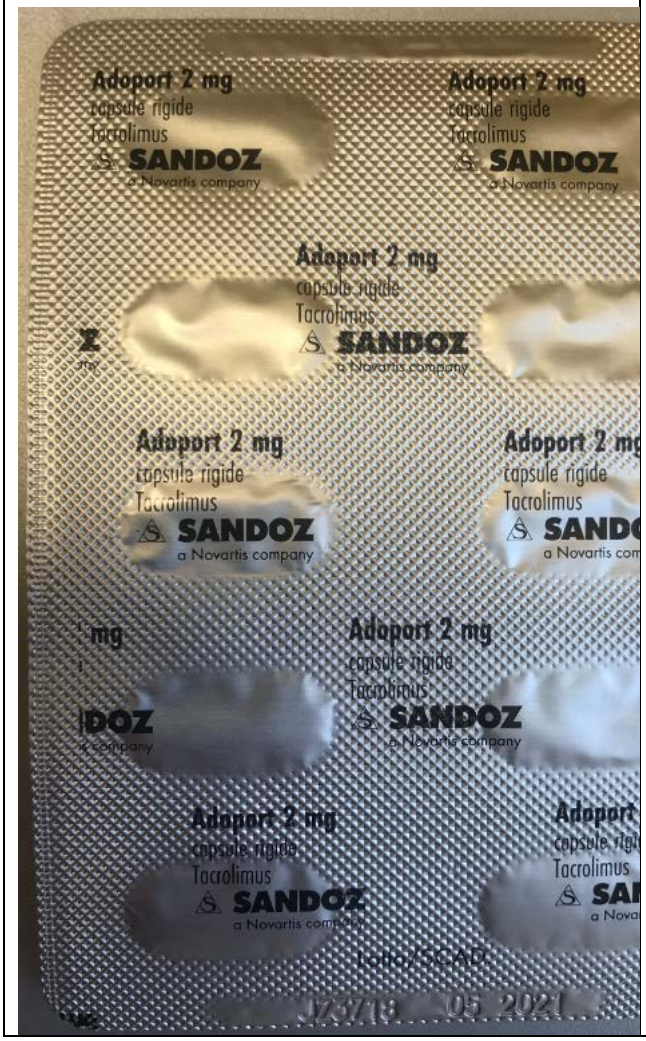
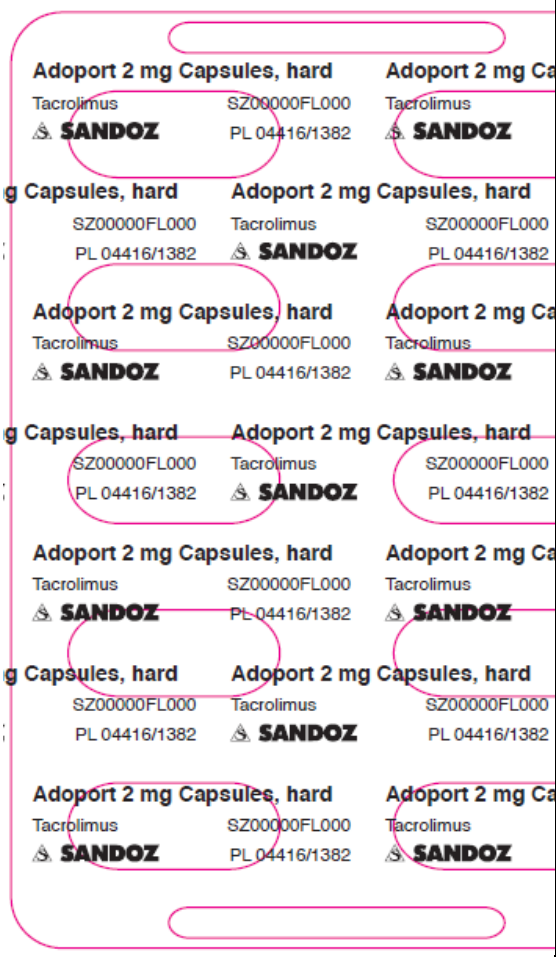
To ensure continuity in supply during the current Covid-19 situation, Sandoz Limited has obtained approval from the MHRA to supply Italian product (batch number JZ3718; 3000 packs; expiry date 31/05/2021), which is expected to be on the UK market from July 2020.

Please note the following:

- This product is considered licenced in the UK.
- The product from Italy has the same formulation as the UK product.
- The product from Italy is manufactured according to the same manufacturing process and quality controls as the UK product.
- The only difference between the UK and repackaged Italian packs is in the foil on the blister pack. The cartons for the repackaged batches are the same as the UK versions. See below for a comparison of the original UK and repackaged UK foils.
- Please refer to the UK approved SPC available on the eMC website https://www.medicines.org.uk/emc and to the UK approved PIL supplied with the packs.
- If you are acting as a distributor of this product several copies of this letter will be enclosed. Please ensure a copy of each letter is sent to all third parties for each pack ordered. If you require additional copies of this letter please contact Sandozgb@EU.propharmagroup.com.
- 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.

The original UK foil and Italian foil present in the repacked product cartons are shown below:

2 mg packed Italian foil	2 mg MHRA approved UK foil
	

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.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form from the Yellow Card section of the MHRA website

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name. Adverse events should also be reported to Sandoz online via uk.patientsafety@novartis.com or through the Pharmacovigilance Information (PVI) tool at www.report.novartis.com.

Company contact point
If you have any questions about this letter or wish more information about Adoport 2 mg capsules, please contact Sandoz Limited Medical Information via email: Sandozgb@EU.propharmagroup.com.

Yours sincerely,

Dr Chris Worth FRCGP
Sandoz UK Ltd. Medical Director