

Date: 08th June 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Adoport (tacrolimus) 2 mg capsules: Interim Supply of Dutch 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.

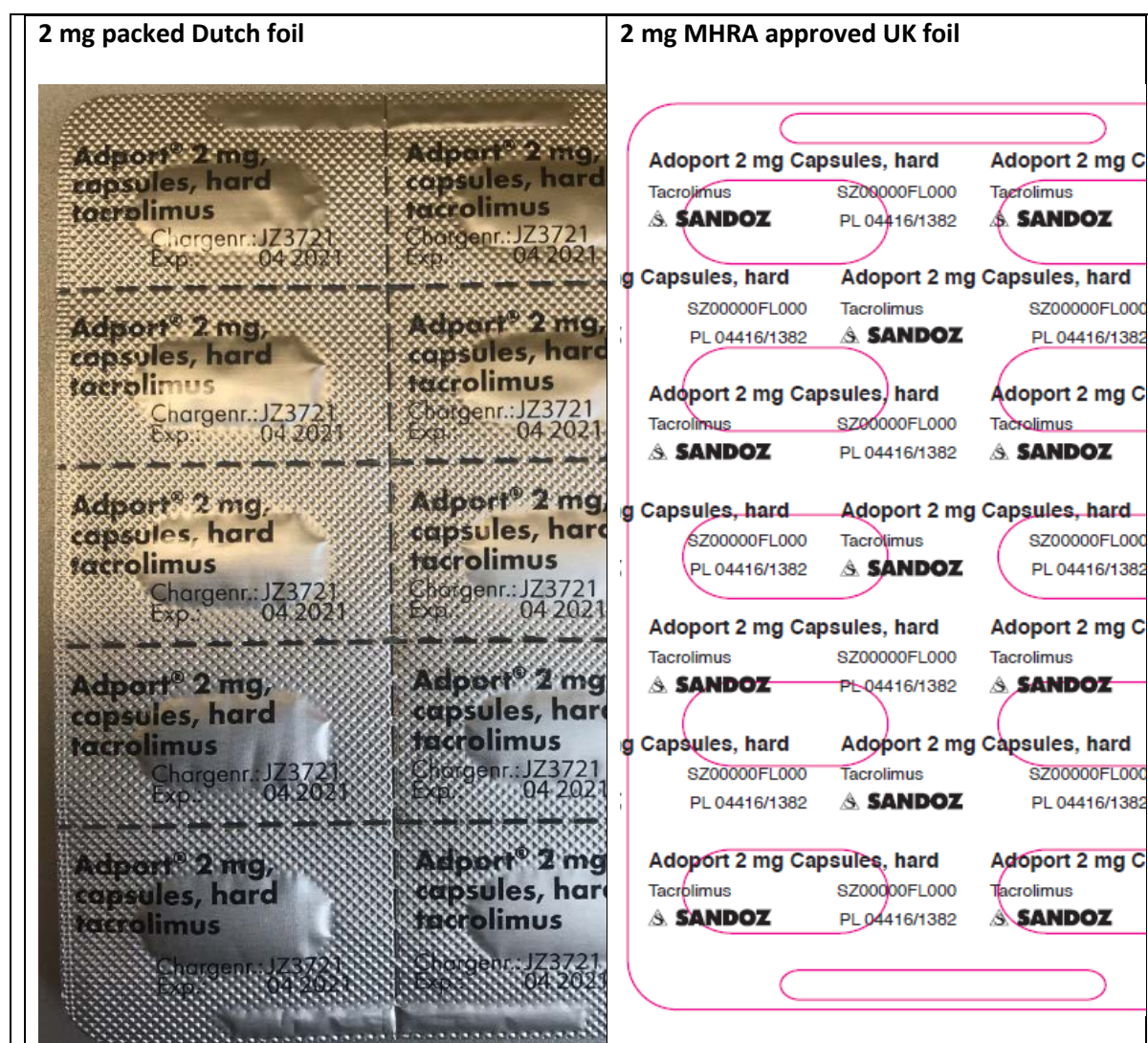
To ensure continuity in supply during the current Covid-19 situation, Sandoz Limited has obtained approval from the MHRA to supply Dutch product (batch number JZ3721; 800 packs; expiry date 30/04/2021), which is expected to be on the UK market from July 2020.

Please note the following:

- This product is considered licenced in the UK.
- The product from The Netherlands has the same formulation as the UK product.
- The product from The Netherlands is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the UK and repacked Dutch packs. The only differences between the UK and repackaged Dutch packs are in the foil on the blister pack and in the product name 'Adport' rather than 'Adoport'. 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 Dutch foil present in the repacked product cartons are shown below:



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,

A handwritten signature in black ink, appearing to read 'C. Worth', with a long horizontal stroke underneath.

Dr Chris Worth FRCGP
Sandoz UK Ltd. Medical Director