SANDOZ A Novartis Division

Direct Healthcare Professional Communication

April 2020

Adoport (tacrolimus) 0.75 and 5 mg capsules – limited number of packs with Italian foil

Dear Healthcare Professional / Homecare company / Wholesaler

This letter is sent in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA).

We previously wrote to you regarding repacked Adoport 2 and 1 mg packs. Please see the enclosed regarding Adoport 0.75 and 5 mg packs.

Summary

- A number of Adoport 0.75 and 5 mg packs, originally destined for Italy, (batch number and expiry date shown below), have been repackaged for the UK.
- The products are exactly the same, the only difference between the UK and repackaged Italian packs is in the foil on the blister pack. See below for a comparison of the original UK and repackaged UK foils.
- These batches were packaged in Slovenia and have been dispatched directly to the UK, never entering Italy.
- If a patient or caregiver contacts you with concerns about seeing a different label for Adoport 0.75 and 5 mg, 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 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.

Table 1: Batch numbers of Adoport 0.75 and 5 mg packed with Italian foil

Product strength	Batch Numbers	Expiry
Adoport 0.75 mg	KB2428 and KB2429	31/05/2021
Adoport 5 mg	JY9789 and JY9790	30/04/2021

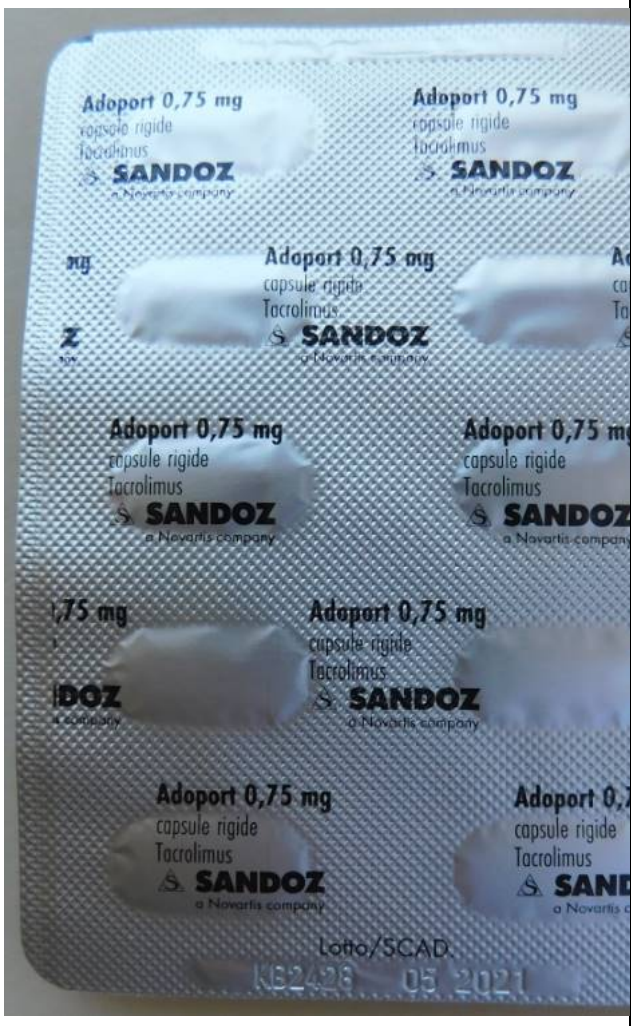
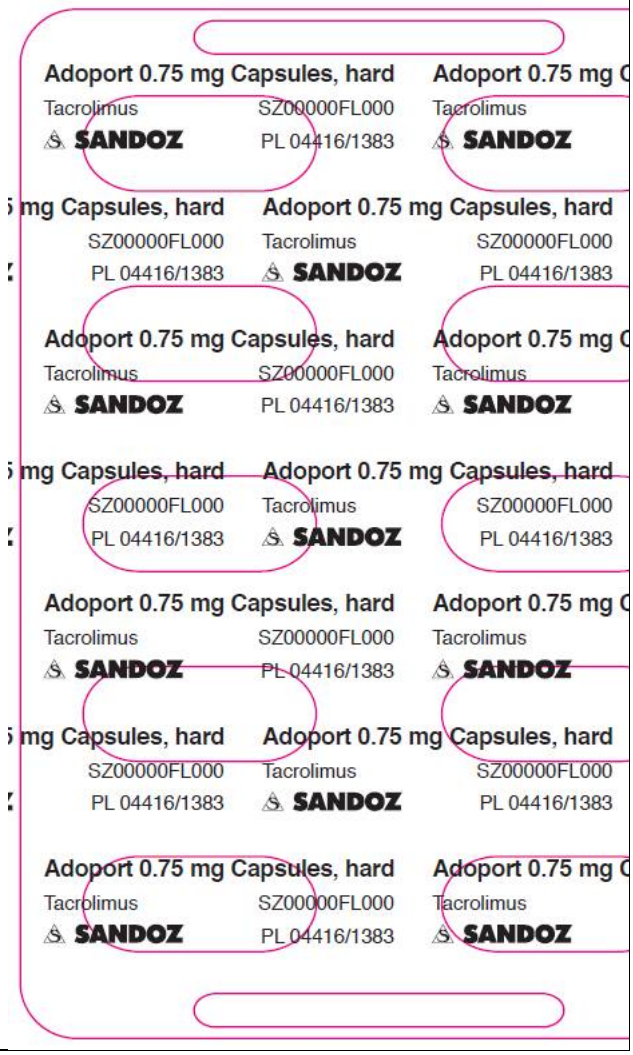
Background

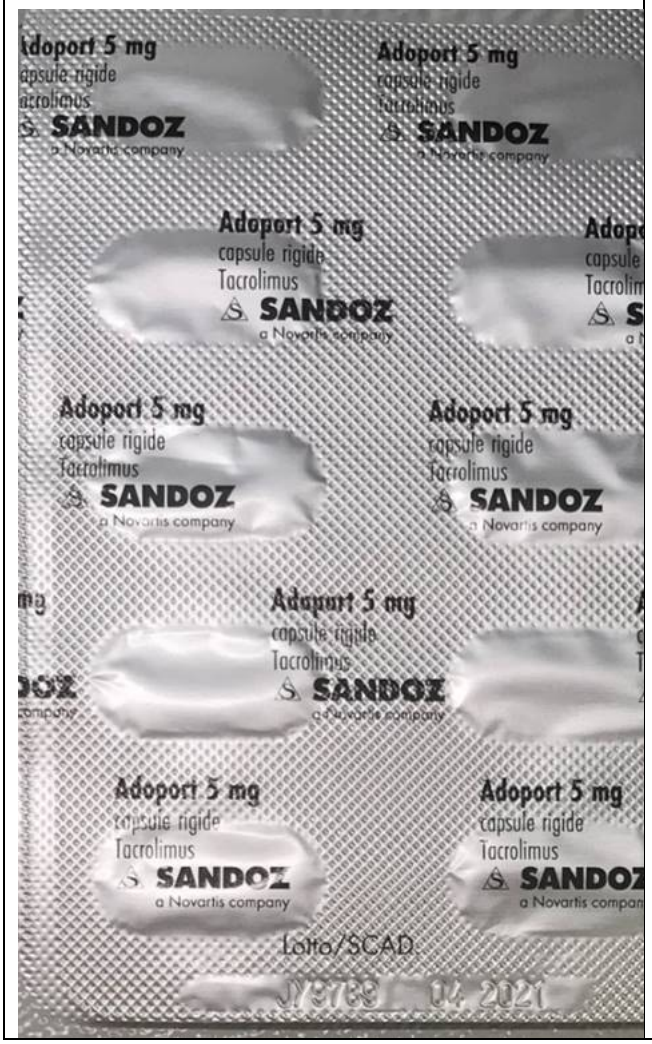
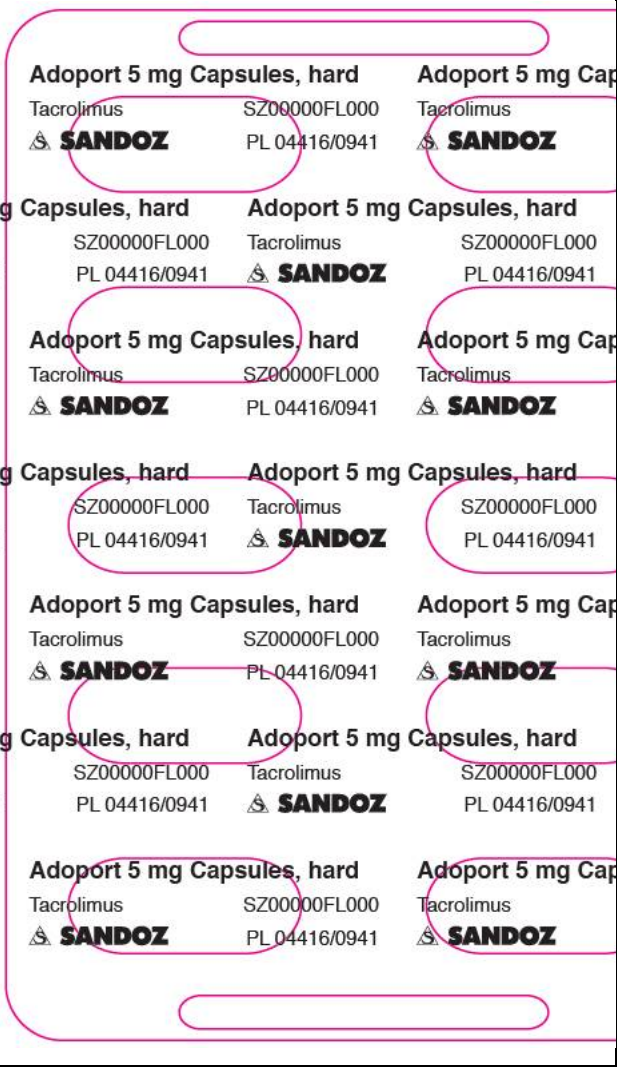
The MHRA have agreed that a limited number of Adoport 0.75 and 5 mg packs originally labelled for use in Italy, can be repackaged for supply and use in the UK. The repackaging will ensure the product is identical to the original UK Adoport packs, with the exception of the foil. The MHRA has agreed that 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 small difference.

Adoport 0.75 and 5 mg are available in cartons containing 50 capsules. The cartons for the repackaged batches are the same as the UK versions, it is only the individual foil on the blister packs that differ. The carton, Patient Information Leaflet and aluminium bag are the UK versions.

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

0.75 mg packed Italian foil	**0.75 mg MHRA approved UK foil**
	

5 mg packed Italian foil	5 mg MHRA approved UK foil
	

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 ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 patient safety information (PSI) tool at www.report.novartis.com.

Further information
Should you require additional information, please contact Medical Information via email: Sandozgb@EU.propharmagroup.com.

Recipients of this Direct Healthcare Professional Communication should bring it to the attention of relevant contacts by copy of this letter.

Yours sincerely,

Dr Chris Worth FRCGP
Sandoz UK Ltd. Medical Director