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7 October 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Prednisolone 20 mg/dose Rectal Foam:
Supply of Packs imported from Ireland

Dear Healthcare Professional,

Summary

To ensure continuity in supply, Chemidex Pharma Ltd has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply packs of Prednisolone Rectal Foam (batch number TACC) imported from Ireland, which is expected to be on the UK market from October 2022 to March 2023.

Please note the following:

The product from Ireland is the same as the UK authorised product, but there are differences in the product labels and patient information leaflet as outlined below.

*-The product name in Ireland is Prednisolone 20 mg Rectal Foam, whereas the product name in the UK is Prednisolone 20 mg/**dose** Rectal Foam*

-The labels (canister and carton) of the Irish product display the authorisation number (PA 22643/3/1) and Authorisation Holder address in Ireland instead of the UK PL number (PL17736/0130) and the UK PL holder address. Also, an indication of the prescription only legal supply status (POM) is missing from the labels of the Irish product.

- The colour scheme of the cartons for the UK product is white/orange, whereas for the Irish product, the colour scheme is white/green.

- The UK Patient Information Leaflet is attached to the carton and should be provided to the patient with the product. Additionally the UK Patient Information Leaflet can be viewed and downloaded from the MHRA website link:
https://mhraproducts4853.blob.core.windows.net/docs/026aefb237a98404fac2513342572bffd5ac26d7

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CHEMIDEX PHARMA

Product Labelling UK and Ireland

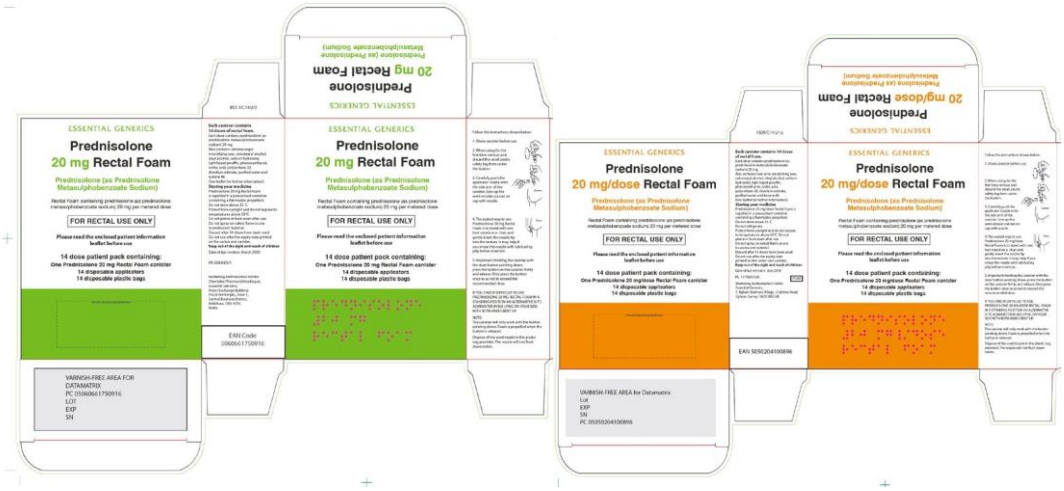

Figure 1- Ireland Carton **UK Carton**

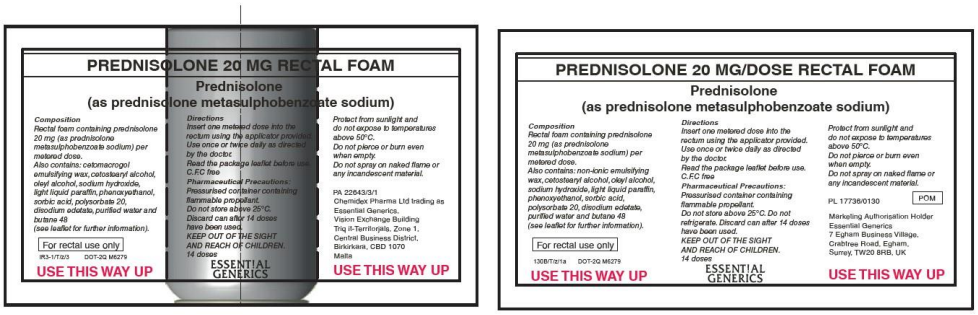

Figure 2- Ireland Canister **UK Canister**

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients. Patients can be reassured that the product from Ireland is identical to the UK product.

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Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, 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 effects can also be reported by calling 0800 731 6789 for free.

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

Company contact point

If you have any questions about this letter or require more information about Prednisolone 20 mg/dose Rectal Foam, please contact Chemidex Pharma Ltd Medical Information on telephone +44 (0) 1784 477 167 or medinfo@essentialpharmaceuticals.com

Yours faithfully,

DocuSigned by:
51F3E8107BCC484...

Colin Brown
Chief Operating Officer
Chemidex Pharma Ltd