

Viatris UK Healthcare Limited, Building 4, Trident Place, Mosquito Way, Hatfield, Herts, AL10 9UL

Date: 28th August 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION Creon® Micro Pancreatin 60.12mg Gastro-resistant Granules: Interim Supply of Spanish Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Viatris is currently experiencing supply disruption with Creon® Micro Pancreatin 60.12mg Gastro-resistant Granules in the UK (Great Britain and Northern Ireland).

To ensure continuity in supply, Viatris has obtained approval from the MHRA to supply Spanish product (batch number 64999; 1,000 packs) which is expected to be on the UK (Great Britain and Northern Ireland) market from September 2024.

Please note the following:

- This product is considered licensed in the UK.
- The product from Spain has the same formulation as the UK (Great Britain and Northern Ireland) product.
- The product from Spain is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain and Northern Ireland) product.
- There are differences between the Spanish and UK product information. The language is different. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- The PIL for Creon Micro is available online at https://www.medicines.org.uk/emc/files/pil.5564.pdf or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with Regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012 and Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Creon® Micro and that the information must be given in English.

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



pSpanish carton image:



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

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 point

If you have any questions about this letter or require more information about Creon®, please contact Viatris Medical Information at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, UK. Telephone: +44 (0)1707 853 000 or email info.uk@viatris.com

Yours faithfully,

Ken Tam Medical lead Viatris UK