NHS Circular: MSAN (2024) 51

Chief Medical Officer Directorate Pharmacy and Medicines Division



28 August 2024

# **Medicine Supply Alert Notice**

# Creon® Micro Pancreatin 60.12mg gastro-resistant granules

Priority: Level 3\*

Valid until: late September 2024

#### Issue

- 1. Creon<sup>®</sup> Micro Pancreatin 60.12mg gastro-resistant granules are in limited supply until late September 2024.
- 2. Creon® 10,000 gastro-resistant capsules are in limited supply into primary care settings via the wholesalers. However, there is a small amount in secondary care which may be used for the patient cohort on Creon® Micro Pancreatin 60.12mg gastro-resistant granules as described in the actions.
- 3. Where Creon® 10,000 gastro-resistant capsules are not suitable, unlicensed supplies may be sourced, lead times vary (see Additional Information).

## **Advice and Actions**

- 4. Health Board hospital pharmacy teams should:
  - proactively place orders for unlicensed supplies to boost available supplies until the next delivery of Creon<sup>®</sup> Micro Pancreatin 60.12mg gastro-resistant granules (see Additional information);
  - review local stock holding and where required, conservatively order stock of Creon<sup>®</sup> Micro
    granules directly from Viatris in line with projected demand until resupply. Further information
    on ordering will be provided to hospital pharmacy teams via National Procurement Medicines
    team at NSS (nss.nhssmedicineshortages@nhs.scot).
- 5. Primary care healthcare professionals should identify patients on Creon® Micro granules and ascertain if they have sufficient stock until resupply; where they have insufficient supply patient/carers should be advised to contact their secondary care specialists for one month's supply of Creon® Micro Pancreatin 60.12mg gastro-resistant granules or for doses of 10000 units or more, GPs can consider prescribing Creon 10,000 gastro-resistant capsules, which may be opened and mixed without crushing (See Additional information).
- 6. Secondary care clinicians should:
  - only initiate patients on Creon<sup>®</sup> Micro Pancreatin 60.12mg gastro-resistant granules where doses of less than 10,000 lipase units are required; and

<sup>\*</sup>https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf

consider prescribing Creon<sup>®</sup> 10,000 gastro-resistant capsules, where patients are on doses
of 10,000 lipase units or more, which may be opened and mixed, without crushing (see
Additional Information).

#### **Additional Information**

## Clinical Information

- 7. Creon® Micro Pancreatin 60.12mg gastro-resistant granules are licensed for the treatment of pancreatic exocrine insufficiency. For certain patients, e.g. infants newly diagnosed with cystic fibrosis, Creon Micro Pancreatin 60.12mg gastro-resistant granules are the only appropriate form of pancreatic enzyme replacement.
- 8. **Creon 10,000 capsules** are licensed for the treatment of pancreatic exocrine insufficiency. They can be swallowed whole, or for ease of administration they may be opened, and the granules taken with acidic fluid or soft food, but without chewing. This could be apple sauce or yoghurt or any fruit juice with a pH less than 5.5, e.g. apple, orange or pineapple juice.
- 9. Many patients adjust their dose according to symptom management, but all patients should be counselled to re-titrate the dose if problems with digestion or weight loss occur.

## Links to further information

- SmPC Creon
- BNFC Pancreatin
- NPPG Position Statement on the shortage of Pancreatic Enzyme Replacement Therapy
- National Patient Safety Alert Shortage of Pancreatic Enzyme Replacement Therapy
- Specialist Pharmacy Services Prescribing and ordering available Pancreatic Enzyme Replacement Therapies
- Specialist Pharmacy Services PERT alternatives and equivalences
- Cystic Fibrosis Trust Creon supply update

## Guidance on ordering and prescribing unlicensed imports

- 10. The following specialist importer has confirmed they can source unlicensed Creon<sup>®</sup> minimicrospheres micro delayed release granules (please note there may be other companies that can also source supplies):
  - Chemys Limited
- 11. The enzyme composition of unlicensed imports may differ from UK licensed products; please refer to corresponding Summary of Product Characteristics for specific product information.
- 12. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:

- <u>The supply of unlicensed medicinal products.</u> Medicines and Healthcare products Regulatory Agency (MHRA)
- <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
- <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC).

## Specialist Pharmacy Service (SPS) website

- 13. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the <u>SPS website</u>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 14. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

## **Enquiries**

15. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <a href="mailto:PharmacyTeam@gov.scot">PharmacyTeam@gov.scot</a> (primary care) or <a href="mailto:NSS.NHSSMedicineShortages@nhs.scot">NSS.NHSSMedicineShortages@nhs.scot</a> (secondary care).