



13 May 2024

## **Medicine Supply Alert Notice**

### **Pancreatic enzyme replacement therapy (PERT)**

**Priority: Level 2\***

**Valid until: Various resupply dates, please see below**

#### **Issue**

1. Creon<sup>®</sup> 10,000 and 25,000 gastro-resistant capsules are in limited supply until 2026.
2. Nutrizym<sup>®</sup> 22 capsules are out of stock until mid-August 2024.
3. Pancrex V<sup>®</sup> capsules and powder remain available but are unable to support an increase in demand.
4. Unlicensed supplies of Creon<sup>®</sup> 10,000 and 25,000 gastro-resistant capsules and alternative brands of PERT may be sourced, lead times vary.
5. Clinical advice has been issued by several professional bodies to support the management of patients in light of these shortages.

#### **Advice and Actions**

6. Clinicians/prescribers should review all patients prescribed PERT and:
  - prescribe a maximum of one month's supply at a time to help ensure there is sufficient stock for all patients;
  - prioritise Creon<sup>®</sup> 10,000 for paediatric patients and patients unable to take Creon<sup>®</sup> 25,000 e.g. patients with swallowing difficulties;
  - prioritise any remaining stock of Nutrizym<sup>®</sup> 22 for patients unable to tolerate Creon<sup>®</sup>;
  - consider prescribing unlicensed imports of PERT only where licensed alternatives are unavailable. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Additional Information section).
7. In addition to the above points, where PERT is prescribed for indications other than cystic fibrosis, clinicians and prescribers should:
  - consider prescribing a proton pump inhibitor or H2 reception antagonist to reduce acid degradation of the PERT and optimise efficacy\*;
  - consider if a dose reduction may be suitable for certain patients based on severity of symptoms\*;
  - where symptoms remain despite a dose of  $\geq 10\,000$  units lipase/kg/day or 100,000 units lipase with a meal, consider whether other causes of the symptoms should be investigated before increasing the dose of PERT further\*;

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

- consider prescribing medication to manage symptom control\*. Please note that medication prescribed for symptom control will not treat malabsorption and should not be considered as alternative to PERT.

\*Please see position statement reference in the Additional Information section below.

## Additional Information

### Clinical Information

8. Creon® gastro-resistant capsules and Nutrizym® 22 capsules are licensed for the treatment of pancreatic exocrine insufficiency. Each preparation contains different amounts of pancreatic enzymes. 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.
9. For advice on the management of reduced doses, symptom control and optimisation of doses please refer to the clinical advice in this [position statement, endorsed by a number of professional bodies](#).

### Links to further information

- [SmPC – Creon® capsules](#)
- [SmPC – Nutrizym 22® capsules](#)
- [SmPC- Pancrex V® capsules and powder](#)
- [BNF - Pancreatin](#)
- [UK Guidelines on the management of pancreatic exocrine insufficiency](#)
- [Cystic Fibrosis Trust - Pancreatic enzyme supplement and cystic fibrosis Pancreatic Cancer UK – Pancreatic enzyme replacement therapy](#)

### Guidance on ordering and prescribing unlicensed imports

10. The following specialist importers have confirmed they can source unlicensed PERT preparations (please note there may be other companies that can also source supplies):
  - Alium (PANCREAZE® Delayed-Release Capsules)
  - Durbin (Zenpep® Delayed-Release Capsules)
  - Mawdsleys (Creon®)
  - Smartway (Creon®)
  - Target (Creon®, PANCREAZE® Delayed-Release Capsules, Viokace® Tablets, Zenpep® Delayed-Release Capsules)
11. **Note: The enzyme composition of unlicensed imports may vary to UK licenced 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 NHS Board or 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:

- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
- [Prescribing unlicensed medicines](#), 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 [SPS website](#). 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 [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot) (primary care) or [NSS.NHSSMedicineShortages@nhs.scot](mailto:NSS.NHSSMedicineShortages@nhs.scot) (secondary care).