Department of Health & Social Care

NHS England

Medicine Supply Notification

MSN/2024/054

Pancreatic enzyme replacement therapy (PERT)

Tier 2 – medium impact*
Date of issue: 09/05/2024
Link: Medicines Supply Tool

Summary

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

Actions Required

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® 10,000 for paediatric patients and patients unable to take Creon® 25,000 e.g., patients with swallowing difficulties;
- prioritise any remaining stock of Nutrizym 22 for patients unable to tolerate Creon®;
- 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 Supporting information).

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 ≥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*;
- 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 supporting information.

*Classification of Tiers can be found at the following link:
https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

Supporting information

Clinical Information

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.

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

The following specialist importers have confirmed they can source unlicensed PERT preparations (please note there may be other companies that can also source supplies):

Note: The enzyme composition of unlicenced imports may vary to UK licenced products, please refer to corresponding Summary of Product Characteristics for specific product information.

- 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)

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust 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),

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:

- xxx (imported)

Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: “**special order**”.

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk.