National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of Pancreatic enzyme replacement therapy (PERT) – Additional actions

Date of issue:	18-Dec-24	Reference no:	NatPSA/2024/013/DHSC

This alert is for action by: Integrated Care Boards and all organisations involved in prescribing, dispensing and oversight of pancreatic enzyme replacement therapy (PERT).

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in pharmacy, community pharmacy, GP practices, and clinical leaders in respiratory, pancreatology, pancreatic surgery, dietetics and cancer.

Explanation of identified safety issue:

This alert contains actions which are in addition to those outlined in the National Patient Safety Alert (NatPSA/2024/007/DHSC) issued on 24th May 2024.

There are limited supplies of pancreatic enzyme replacement therapies (PERT).

- Creon® 10,000 and 25,000 capsules remain in limited supply until 2026.
- Nutrizym® 22 capsules and Pancrex V® capsules and powder are intermittently available but are unable to fully cover the gap in supply.

The supply disruption of Creon® capsules is due to limited availability of raw ingredients and manufacturing capacity constraints to produce volumes needed to meet demand. There are regular deliveries to wholesalers, two to three times each month, of both strengths to allow for equitable distribution. However, the volumes are insufficient to meet full demand. Therefore out of stock periods continue between each delivery.

Production of Nutrizym® 22 capsules has been increased and supplies are being released monthly, however this increase is unable to fully cover the gap in supply. There are intermittent deliveries of Pancrex V® capsules and powder but these are also unable to support an uplift.

Unlicensed imports of Creon® capsules and alternative brands of PERT can be sourced, lead times vary - see Note A.

Actions required

Actions for clinicians and prescribers of PERT to be completed by 31/01/2025 and to remain in place *only until the supply issues have resolved* (see SPS Medicine Supply Tool for resolution dates):

1. Clinicians should continue to follow the actions set out in the National Patient Safety Alert (NatPSA/2024/007/DHSC) issued on 24th May 2024.
2. NHS provider trust pharmacy procurement teams should ensure that where quantities greater than current demand are required, unlicensed imports should be considered. NOTE A
3. To ensure that patients are not left without PERT, Integrated Care Boards (ICBs) should:
   a. put in place a local mitigation plan for instances when patients are unable to obtain stock from their community pharmacy or dispensing GP.
   b. cascade any local management plan to all community pharmacies and GP practices within the region, as well as local trust pharmacy teams. NOTE B

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Clinical Information

PERT is indicated for the treatment of pancreatic exocrine insufficiency such as in cystic fibrosis, pancreatic cancer and pancreatitis. There is no clinical alternative to PERT. 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 updates on stock availability, optimisation of doses and symptom control, as well as information on switching between products and available unlicensed preparations, please refer to the SPS webpage 'prescribing and ordering available pancreatic enzyme replacement therapies'.

NOTE A: The supply issue is impacting primary care suppliers to a much greater extent than secondary care suppliers due to the supply channels available to each sector. This is increasing pressure on secondary care supplies as some patients unable to obtain stock locally are being referred to local secondary care supplier.

Several specialist importers have confirmed they can source unlicensed PERT; please note there may be other companies that can also source supplies. The enzyme composition of unlicensed imports may differ from UK licensed products; please refer to the datasheet accompanying these products.

For a list of specialist importers and for guidance on ordering and prescribing unlicensed imports see here.

NOTE B: Many ICB regions have escalation processes in place for when patients are unable to access PERT from their community pharmacy or GP. Examples of local regional mitigation plans produced by ICBs include:

- Centralised ordering process for unlicenced imports to support local community pharmacies. For example, see Community Pharmacy Hampshire & Isle of Wight
- Collaboration between community pharmacies, GPs and local trusts to create an emergency pathway to access PERT

References:

- SmPC - PERT
- BNF: Pancreatin
- SPS - Prescribing and ordering available pancreatic enzyme replacement therapies
- SPS Medicine Supply Tool
- NHS BSA Serious Shortage Protocols
- National Patient Safety Alert - Shortage of Pancreatic enzyme replacement therapy (PERT)
- Community Pharmacy Hampshire & Isle of Wight - Imported Creon Alternative

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Services; Medicines Shortage Response Group; NHS England; national clinical experts in Cystic Fibrosis, Pancreatology, Pancreatic Cancer, Gastroenterology and national patient safety team; Medicine and Healthcare products Regulatory Agency and the Devolved Governments

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.