

# 18 February 2025

## Guidance note for managing Pancreatic Enzyme Replacement Therapy supply (PERT) shortages - General Practice

This guidance note applies to prescribers in general practice and primary care networks. It has been developed to support the implementation of the National Patient Safety Alert: Shortage of Pancreatic Enzyme Replacement Therapy (PERT) Additional actions Reference Number: (<u>NatPSA/2024/013/DHSC</u>).

Pancreatic Enzyme Replacement therapy (PERT) is for the treatment of pancreatic exocrine insufficiency in conditions such as cystic fibrosis, pancreatic cancer and pancreatitis. **Patients cannot be left without PERT because it can cause severe harm**. This can lead to hypoglycaemia, severe bowel symptoms, poor absorption of other medications and weight loss. This document summarises the current challenges with PERT and provides local advice and actions.

#### Summary of the current issues (January 2025)

There are limited supplies of PERT in the UK. It is important that we take steps to ensure that patients in North East London (NEL) can continue to access the medicines they need, when they need them. Please reassure patients that supplies of PERT are continuing to reach the UK. Below is a summary of current supply distribution:

- Creon® 25000 and Creon ®10000 capsules: Limited supply until 2 January 2026, capped quantities until 2026. Supply disruption is due to limited availability of the active pharmaceutical ingredients and manufacturing constraints. There are <u>Serious Shortage Protocols (SSPs)</u> for Creon® 25000 capsules and Creon® 10000 capsules.
- **Nutrizym® 22 capsules**: Limited supply. Prioritised for those unable to tolerate Creon preparations. Supply disruption is caused by increased demand due to reduction in Creon® preparation supply.
- Pancrex V® 125mg capsules: Unavailable. Expected to be out of stock until 3 Jan 2025.
- Pancrex V® 340mg capsules: Unavailable. Expected to be out of stock until 6 June 2025.
- Pancrex V® oral powder: Unavailable. Expected to be out of stock until 2 May 2025.
- Unlicensed imports e.g. Creon® Imported, Pangrol®: Lead times vary (ensure orders are placed within appropriate time frames). Only consider where licensed alternatives are unavailable.

Pangrol® is an unlicensed imported pancreatic enzyme preparation available in equivalent strengths to Creon® (licensed and imported). 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 Specialist Pharmacy Service (SPS) webpage <u>'prescribing and ordering available pancreatic enzyme replacement therapies'</u>

### Actions for prescribers in general practice

- Ensure prescriptions of PERT are for a maximum of one month's supply.
- Prescribe licensed PERT first.
  - Creon® 10000 capsules should be reserved for people unable to take Creon® 25000 capsules e.g. children and people who are unable to swallow larger capsules.

Title	Guidance note for managing Pancreatic Enzyme Replacement Therapy Supply – General Practice v 1.0		
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- Creon® Micro Pancreatin 60.12mg capsules are prioritised for children and those with dysphagia who are unable to open the Creon® capsules.
- Nutrizym® 22 should be prioritised for people who are unable to tolerate Creon®. This is not suitable for children under 15 years of age.
- Pancrex® V powder should be prioritised for patients receiving enteral feeding tubes. This is not an appropriate product for patients to take orally in most cases.
- Issue licensed PERT as a single item on an EPS prescription or provide patients with a prescription token. Issue repeat prescriptions ahead of patients need – patients are being advised to allow two weeks ahead of need to allow time for prescriptions to be filled.
- Please make sure that GP practice prescription management teams are aware of this deviation from usual practice. Do not post-date prescriptions, use the pharmacy text box to explain why an early prescription is being submitted.
- Prescribe unlicensed PERT imports only where licensed alternatives are unavailable, working with community pharmacy teams to ensure orders are placed within appropriate time frames.
- Ensure prescriptions for <u>supply of unlicensed PERT preparations</u> are written accurately. Please note community pharmacies cannot issue unlicensed PERT against a prescription for licensed PERT.
- Please note Pangrol® should be issued on a handwritten FP10 paper prescription and should detail:
  - Name of medication including strength and formulation (Imported)
    - Pangrol 10,000/25,000\* gastro resistant capsules (Imported) \* (delete as appropriate)
  - Special Order
  - o **Dosage** instructions for patient
  - **Quantity** (note Pangrol® pack size is 200 capsules)
- Patients should be informed of the rationale for the use of an unlicensed imported product and adequate justification provided. This should also be documented in the patient's medical record as per <u>GMC requirements</u>.
- Paediatric, neonatal and cystic fibrosis patients should continue to liaise with their specialist teams for advice about disease management in pancreatic insufficiency and PERT regimens
  - Please consult the <u>national position</u> statement for further clinical information on managing PERT shortages in adults living with cystic fibrosis and other conditions.
  - Please consult the <u>position statement</u> from the neonatal and paediatric pharmacy group for further clinical considerations for managing PERT shortages in children.
- Immediately refer patients to a specialist for advice on alternative treatments if above options are not suitable.

### Actions for prescribers in secondary care

- Ensure prescriptions of PERT are for **a maximum of one month's supply**.
- Maintain patients under specialist care on licensed PERT preparations where possible
  - Creon® 10000 capsules should be reserved for people unable to take Creon® 25000 capsules e.g. children and people who are unable to swallow larger capsules.
  - Creon® Micro Pancreatin 60.12mg capsules are prioritised for children and those with dysphagia who are unable to open the Creon® capsules.
  - Nutrizym® 22 should be prioritised for people who are unable to tolerate Creon®. This is not suitable for children under 15 years of age.
  - Pancrex® V powder should be prioritised for patients receiving enteral feeding tubes. This is not an appropriate product for patients to take orally in most cases
- Liaise with trust pharmacy teams if patients managed and prescribed PERT by specialists are having trouble obtaining licensed PERT preparations.
- Prescribe unlicensed PERT imports only where licensed alternatives are unavailable.

Please continue to record suspected adverse drug reactions to the <u>Yellow Card scheme</u>. Please continue to record medicine patient safety incidents to <u>Learning From Patient Safety Events</u>

#### References

- 1. National Patient Safety Alert <u>Shortage of Pancreatic enzyme replacement therapy (PERT) Additional actions Reference Number:</u> (NatPSA/2024/013/DHSC)
- 2. National Patient Safety Alert Shortage of Pancreatic enzyme replacement therapy (PERT) Reference Number: NatPSA/2024/007/DHSC)
- 3. Specialist Pharmacy Service Medicines Supply Tool https://www.sps.nhs.uk/home/tools/medicines-supply-tool/ (accessed 25/01/2025)
- 4. Correspondence from Oxford Pharmacy Stores https://oxfordpharmacystore.co.uk/
- 5. NHS Business Services Agency Serious Shurtage Protocols <u>https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps</u>
- Nutrition Interest Group of the Pancreatic Society of Great Britain and Ireland (NIGPS), Cystic Fibrosis Specialist Group and Gastroenterology Specialist Group, British Dietetic Association (17/11/24) <u>https://www.psgbi.org/position-statement-pert-shortage/</u> (accessed 28/01/25)
- Neonatal & Paediatric Pharmacists Group Position statement 2024-01 Shortage of Pancreatic Enzyme Replacement Therapy (August 2024). <u>https://nppg.org.uk/wp-content/uploads/2024/08/NPPG-Position-Statement-PERT-V1.pdf?UNLID=231770520249542647</u> (accessed 28/01/25)
- Community Pharmacy England Supply of Unlicensed PERT preparations (03/02/25) <u>https://cpe.org.uk/our-news/supply-of-unlicensed-pert-preparations/</u> (accessed 05/02/25)