

# 18 February 2025

## Guidance note for managing Pancreatic Enzyme Replacement Therapy supply (PERT) shortages – Community Pharmacy

This guidance note applies to community pharmacies. 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>'.

Title	Guidance note for managing Pancreatic Enzyme Replacement Therapy Supply – Community Pharmacy v 1.0			
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## Actions for community pharmacies

- Please reassure patients that supplies of PERT are continuing to reach the UK and avoid the accumulation of excess supplies.
- Pharmacies presented with repeat prescriptions should only supply the equivalent to one month's supply in accordance with the Serious Shortage Protocols <u>SSP060 and SSP061</u> and endorse accordingly.
- Pharmacies are reminded to continue to adhere to the requirements outlined in the NatPSA.
- Continue to source licensed PERT through your usual wholesalers' stock which is usually released from manufacturers to wholesalers three times a month.
- Please secure the most cost-effective supply of unlicensed PERT (which may be through your usual wholesaler or Oxford Pharmacy Store (OPS)).
- If patients ask to try a different pharmacy please return the prescription to the spine and give a printed token to the patient.
- If patients are due to run out of licensed PERT in the next 10 days and there are no other preparations available, consider ordering Pangrol®. NEL pharmacies can access centralised stock of Pangrol® ordered from the <u>Oxford Pharmacy Store</u> (OPS).
- Please contact the GP to request a **handwritten paper FP10 prescription** for Pangrol® as soon as possible.
- Pharmacies will be able to order Pangrol<sup>®</sup> from the OPS if they have an account set up with them. Existing customers should continue to place orders as usual.
- For new customers, <u>Register for a New Account</u> or complete and return a completed <u>OPS New</u> <u>Customer Verification Form</u> to set up an account with OPS (this may take up to 3 days).
- Please note the following important details for returning the New Customer Verification Forms to OPS:
  - Ensure the Customer Details and Customer Verification sections are completed.
  - Include the Supply of Unlicensed Medicine Confirmation Form.
  - OPS cannot accept typed name signatures; please ensure the documents have either an electronic or a wet signature.
  - Return the signed forms along with a Purchase Order (PO) to ops.orders@oxfordhealth.nhs.uk
  - Without these forms and a PO, they will be unable to set up your account.

#### Please send orders to <u>ops.orders@oxfordhealth.nhs.uk</u> or via online order form accessible via <u>Oxford Pharmacy Store: Order Information</u>

### How to dispense prescriptions for Pangrol®

- There is a clinical difference between Pangrol® and Creon®. Pharmacist should counsel patients on how to take Pangrol®.
  - The Pangrol® PIL states: "If you have difficulty swallowing the capsule whole, you can also carefully open it over a suitable container by pulling it apart and swallowing only the contents with a little liquid immediately and without chewing".
  - The Creon® PIL states: If the capsules cannot be taken whole, "open the capsules and mix the granules (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt). Swallow the mixture straight away, without chewing".
- When dispensing please print and include the relevant patient information leaflet:
  - Patient Information Leaflet: Pangrol® 10 000
  - Patient Information Leaflet: Pangrol® 25 000

#### How to endorse prescriptions for Pangrol®

Make sure any Pangrol® paper FP10 prescriptions are endorsed with the following information:

- Amount dispensed over pack size (200) used.
- **Invoice price per pack size** from which the order was supplied less any discount or rebate; make sure to include delivery cost.

- Manufacturers'/importers' (Target Healthcare) MHRA licence number which is; MS43086/ WDA(H)43086.
- Batch number of the product supplied;
- The letters 'SP' to indicate it is a special.

Refer to How should I endorse a special, unlicensed or imported drug?

### Actions for prescribers in secondary care

- Ensure prescriptions for 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 Learning From Patient Safety Events.

#### References

- 1. National Patient Safety Alert <u>Shortage of Pancreatic enzyme replacement therapy (PERT) Additional actions Reference Number: (</u><u>NatPSA/2024/013/DHSC</u>)
- 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 <u>https://www.sps.nhs.uk/home/tools/medicines-supply-tool/</u> (accessed 25/01/2025)
- 4. Correspondence from Oxford Pharmacy Stores <u>https://oxfordpharmacystore.co.uk/</u>
- NHS Business Services Agency Serious Shurtage Protocols <u>https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps</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)
- 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)
- Pangrol<sup>®</sup> 10,000 Patient Information Leaflet. Available at: <u>https://cpsc.org.uk/download\_file/view/4869/3285. Accessed on 06/02/25</u>
  Electronic medicines compendium: Creon 10,000<sup>®</sup> Capsules Patient Information Leaflet. Available at
- Electronic medicines compendium: Creon 10,000° Capsules Patient Information Leanet. Avail <u>https://www.medicines.org.uk/emc/product/1167/pil</u>. (accessed on 06/02/25)