

# Pancreatic Enzyme Replacement Therapy (PERT) Shortage information and local guidance

This is a summary of the current supply challenges with Pancreatic Enzyme Replacement Therapy supply (PERT) and provides advice and actions for prescribers, patients and community pharmacy/dispensing practices. Patients must not be left without any PERT. This can lead to hypoglycaemia, severe bowel symptoms, poor absorption of other medications and weight loss.

## 1. Summary of current supply issues (May 2025):

Table 1: Supply status and reason for supply issues for PERT in the UK:

Creon® 10000 capsules, Creon® 25000 capsules Creon <sup>®</sup> Micro Pancreatin 60.12mg gastro-resistant granules	Nutrizym® 22 capsules	Pancrex V® capsules and powder
Available currently but in limited, capped quantities until 2027	Available but are unable to support increased demand	Subject to supply disruption
Supply disruption is due to limited availability of the active pharmaceutical ingredients and manufacturing constraints	Supply disruption is caused by increased demand due to reduction in Creon® preparation supply	Supply disruption is caused by increased demand due to reduction in Creon® preparation supply

## 2. Key points:

- For background please see <u>National Patient Safety Alert for PERT</u> alongside <u>Serious Shortage</u> <u>Protocols</u> (SSPs) for Creon® 25000 capsules and Creon® 10000 capsules
- Current PERT supply status can be checked on the <u>SPS website</u>.
- The <u>SPS Medicines supply tool</u> may help to determine the volumes of alternative products to prescribe, but only lists licensed products and the following points should be considered:
  - 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.
  - Nutrizym® 22 should be prioritised for people who are unable to tolerate Creon® preparation. Please note Nutrizym® 22 is not suitable for children under 15 years of age.
  - Creon® Micro Pancreatin 60.12mg gastro-resistant granules should be prioritised for children and people with swallowing difficulties.
  - Pancrex V Powder should be prioritised for patients with enteral feeding tubes, this is not an appropriate product for patients to take orally in most cases.



## 3. Clinical advice:

Where PERT is prescribed to adults for indications other than cystic fibrosis, consider the following, described in more detail in the <u>national position statement</u>:

- prescribing a proton pump inhibitor or H2 receptor antagonist to reduce acid degradation of PERT and optimise efficacy.
- if a dose reduction may be suitable for 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, whether other causes of the symptoms should be investigated.
- prescribing medication to manage symptom control noting that this will not treat malabsorption and is not an alternative to PERT.

## 4. Advice for prescribers:

#### 4.1 Suggested order of preference for PERT choice:

Licensed products first line Pangrol import via Oxford Pharmacy Stores Contact ICB meds opt team in urgent/emergency

- Licensed preparations are preferable to unlicensed products however supply is such that the need to prescribe/source unlicensed supply is likely to be high pharmacies/dispensing contractors may ask for prescriptions to be rewritten in accordance with supply options.
- The ICB is working with Oxford Pharmacy Stores to secure a centralised route for imported pancreatic enzymes where licensed alternatives are unavailable see below.
- As of April 2025, **Creon**® is being supplied to community pharmacy via a single wholesaler, with monthly capped allocations. Stock is released from manufacturer to wholesaler three times per month. *Patients may require their monthly allocation to be split across separate prescriptions to ensure they can access their full allocation.*
- If community pharmacies are unable to access Creon® preparations and patients are due to run out of their medication, please prescribe imported Pangrol® pancreatic enzyme preparation. Community pharmacies cannot issue Pangrol® imports against a prescription for Creon®.
- As of April 2025, **Pangrol® is listed on electronic clinical systems** as an unlicensed import paper prescriptions are no longer required.
- Where applicable, 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>.



#### 4.2 Repeat prescribing advice – for all practice staff:

Ensure prescriptions for PERT are for a **maximum of 1 month supply**. Typically for adults this will be a maximum of 500 Creon® 25000/ Nutrizym® 22 capsules per month.

Issue repeat prescriptions ahead of time – patients are being advised to order 2 weeks ahead to allow time for prescriptions to be filled

Ensure 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

Close working and communication between prescribers and dispensing contractors to ensure that patients are not left without supplies – have you got a system in place to communicate quickly with patients and between GP practice/pharmacy?

#### 4.3 When to escalate

If there is no available stock either licensed or unlicensed and there is urgent need and otherwise the patient will go without, please seek advice from the ICB pharmacy and medicines optimisation team (<u>hnyicb.rxline@nhs.net</u>). PERT supplies may be able to be sourced from a local acute trust but only in emergencies.

### 5. Guidance for community pharmacy/dispensing practices:

#### 5.1 General points for trying to secure stock:

- Please reassure patients that supplies of pancreatic enzymes are continuing to reach the UK and that Creon® and Nutrizym® products have not been discontinued. The current stock issues will be continuing intermittently, but pancreatic enzymes are still available to prescribe.
- Pharmacies presented with repeat prescription for Creon® preparations should only supply the
  equivalent to one month's supply in accordance with <u>SSP060 and SSP061</u> and endorse as
  directed by the SSP.
- As of April 2025, Creon® is only available to community pharmacy via Alliance wholesaler. Stock allocations have been implemented limiting the amount of Creon® each community pharmacy can request. Please try and order UK Creon in the first instance, stock is released from the manufacturer to wholesaler three times a month.
- If the required PERT preparation is showing as out of stock, please order to add onto the backorder list. Patients are being advised to submit requests 2 weeks in advance of need.
- If patients ask to try to locate stock via a different pharmacy, please return the prescription to the spine and give a printed token to the patient.



#### 5.2 Ordering imported products

- If there are no obvious supplies of licensed products available and the patient has 10 days or less stock, then please seek to obtain unlicensed supplies.
- Some wholesalers are now able to access supplies of Pangrol<sup>®</sup> as an imported PERT product.
- The ICB has agreed with Oxford Pharmacy Store (OPS) that it is able to secure imported stocks of pancreatic enzymes currently Pangrol.
- Pangrol<sup>®</sup> is unlicensed imported pancreatic enzyme preparation available in equivalent strengths to Creon:

Licensed product	Equivalent unlicensed Pangrol	
Creon® 10000	Pangrol <sup>®</sup> 10,000	Pack size 200 capsules ( 2 x
	_	100 packs banded together)
Creon® 25000	Pangrol <sup>®</sup> 25,000	Pack size 200 capsules (2 x
	_	100 packs banded together)

#### How to order imported Pangrol<sup>®</sup> stock?

Pangrol<sup>®</sup> stock can be imported via OPS with an expected lead time for delivery of 1-2 days. The OPS should only be used when licensed stock is not available from a wholesaler and patient has 10 days or less stock left.

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 the completed <u>OPS New Customer Verification Form</u> to set up an account with Oxford Pharmacy Store (initial setup make take up to 2-3 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 Medicinal 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 <u>ops.orders@oxfordhealth.nhs.uk</u>
  - 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 accessible using the online order form <u>Oxford Pharmacy Store: Order Information</u>

- You will need to request a new prescription from the GP practice to ensure that you are reimbursed appropriately for Pangrol<sup>®</sup>.
- As of April 2025, Pangrol<sup>®</sup> is listed as an unlicensed import in the Drug Tariff, so paper prescriptions are no longer required.
- Pangrol prescriptions should be written as: Pangrol<sup>®</sup> 10,000 or 25,000 gastro resistant capsules (Imported)



 Pangrol prescriptions should be endorsed by the pharmacy as a non-Part VIIIB special as per NHS BSA guidance:

https://faq.nhsbsa.nhs.uk/knowledgebase/article/KA-03292/en-us

- When dispensing please print and include the relevant Patient Information Leaflet (PIL):
  - <u>Pangrol<sup>®</sup> 10,000</u>
  - Pangrol<sup>®</sup> 25,000



## **Advice for Patients:**

# Attachment to enable document to be sent to patients

