

Pancreatic Enzyme Replacement Therapy (PERT) Shortage information and local actions

This document summarises the current challenges with Pancreatic Enzyme Replacement Therapy supply (PERT) and provides advice and actions for prescribers, patients and community pharmacy. It has been broken down into 4 sections:

Summary of Current Issues

Section 1 - Actions required for clinicians and prescribers

Section 2 - Advice for community pharmacists

Section 3 - Advice for patients

Summary of Current issues (November 2024):

There are limited supplies of pancreatic enzyme replacement therapies in the UK:

- Creon® 10000 capsules, Creon® 25000 capsules and Creon Micro Pancreatin 60.12mg gastro-resistant granules are available currently but in limited, capped quantities until 2026.
 - Supply disruption is due to limited availability of the active pharmaceutical ingredients and manufacturing constraints.
- Nutrizym® 22 capsules are available but are unable to support increased demand.
 - Supply disruption is caused by increased demand due to reduction in Creon® preparation supply.
- Pancrex V® capsules and powder are subject to supply disruption.
 - Supply disruption is caused by increased demand due to reduction in Creon® preparation supply.
- A National Patient Safety Alert has been issued for the <u>Shortage of Pancreatic enzyme</u> replacement therapy (PERT) alongside <u>Serious Shortage Protocols</u> (SSPs) for Creon® 25000 capsules and Creon® 10000 capsules.

Current status of pancreatic enzyme supplies can be checked on the SPS website.

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.

Advice for clinicians and prescribers:

- 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.
- Ensure prescriptions of 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 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 2
 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.
- Patients must not be left without any PERT. This can lead to hypoglycaemia, severe bowel symptoms, poor absorption of other medications and weight loss.
- Surrey Heartlands is working with Oxford Pharmacy Store to secure a centralised route for imported pancreatic enzymes where licensed alternatives are unavailable. 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.
 Prescriptions for Pangrol should be issued on a FP10 paper prescription and should detail:
 - Pangrol 10,000/25,000* gastro resistant capsules (Imported) * (delete as appropriate)
 - Special Order
 - Dosage instructions for patient
 - Quantity (Pangrol comes in 200 capsule packs)

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 GMC requirements.

Dispensing practices should follow guidance in the Community Pharmacy Section to dispense the imported Pangrol.

Where PERT is prescribed to adults for indications other than cystic fibrosis, clinicians and prescribers should consider the following, described in more detail in the <u>national position</u> <u>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.

Advice for community pharmacies

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.

If the patients 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.

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Imported products

Some wholesalers are now able to access supplies of Pangrol as an imported PERT product. Surrey Heartlands is working with Oxford Pharmacy Store (OPS) to secure a centralised route for imported pancreatic enzymes. If patients are due to run out of PERT in the next 10 days and there is no Creon available through usual routes, consider ordering imported Pangrol (either through your usual wholesaler or through OPS), and requesting a new prescription to ensure full costs are covered. Pangrol is unlicensed imported pancreatic enzyme preparation available in equivalent strengths to Creon.

Licensed product	Equivalent unlicensed imports	
Creon 10000	Pangrol 10,000	Pack size 200 capsules (2 x 100 packs banded together)
Creon 25000	Pangrol 25,000	Pack size 200 capsules (2 x 100 packs banded together)

Please liaise with patients and prescribers where an unlicensed import product is required to fill a prescription. Where a prescriber needs to prescribe an imported product, a handwritten FP10 paper prescription should be requested clearly showing that the supply of the import is intended. The prescription should detail the imported product:

Pangrol 10,000 or 25,000 gastro resistant capsules (Imported)

and 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):

- Pangrol 10,000
- Pangrol 25,000

Endorsing the Prescription (as a non-Part VIIIB special)

Make sure any Pangrol scripts 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;
- SP

Make sure you claim all costs associated with ordering this stock when you dispense it.

How to order imported Pangrol stock?

Ringfenced stock for pharmacies within Surrey Heartlands ICB can be ordered from the Oxford Pharmacy Store (OPS), with an expected lead time for delivery of 1-2 days.

You will need an account with OPS, if you do not have one already, email ops.orders@oxfordhealth.nhs.uk to set one up (this may take up to 3 days). You will need to supply the following details: Pharmacy Name, Address, Email for remittance, ODS code.

Ordering imported stock from OPS

Send orders to ops.orders@oxfordhealth.nhs.uk

Advice for patients

Why is this guidance needed?

In the UK, there currently (November 2024) is a shortage of a type of medicine called pancreatic enzyme replacement therapy (PERT) that some people need to help them digest food properly. This medicine is important for people whose pancreas, an organ in the body, doesn't make enough enzymes. Enzymes help the body break down food so it can be used for energy. The shortage happened because there have been problems manufacturing enough of this medicine, and it's been hard to get the ingredients needed to produce it. This has made it difficult for some people to get the medicine they need, so Surrey Heartlands ICB, along with community pharmacies, hospitals and GP practices are working on finding other solutions to help people get the medication they need until the shortage is over. It is predicted that the supply of some PERT medicines will not return to full availability until 2026.

We understand the anxiety the current supply issues are causing and are working to help everyone who needs pancreatic enzymes (PERT) to get the medications they need.

What should I do if I am having problems getting my PERT prescription?

- Place your prescription request 2 weeks earlier than usual to give your community pharmacy time to source your medication.
- Your GP should provide your PERT prescription as a single item on a prescription this allows you to take the prescription token to different pharmacies if there is available stock.
- Some community pharmacies have online stock checking services, which may be helpful. Call ahead to confirm stock before making a special visit to a pharmacy.
- If your pharmacy let you know your PERT is out of stock please ask them to order it anyway so the order is logged and will be filled when the next shipment of PERT arrives in the UK.
- Let your GP know if you are not able to get a prescription filled and have only 10 days' supply of PERT remaining. There is now a process available to access imported medication. You may be prescribed a different product which is equivalent to your usual PERT. Please talk to your community pharmacist about any queries.

Other important points

- To help the enzymes work best remember to take your PERT throughout your meals rather than all at the start, middle or end.
- Don't stockpile medications this makes supply issues worse for everyone. GPs have been advised by the Department for Health to issue prescriptions for 1 month's supply of PERT at a time.
- Do not borrow or share medication with other patients or buy medication on the internet.

Where to get further information

There are specialist support lines available where you can speak to nurses for advice and guidance through organisations like Pancreatic Cancer UK or the CF Trust.

<u>This resource</u> may be helpful if you are an adult having trouble accessing PERT. It provides advice to minimise the impact on your symptoms and quality of life should you be unable to access your normal supply of PERT. This resource is not suitable for children or those with cystic fibrosis.