## Pancreatic Enzyme Replacement Therapy (PERT)

## Shortage information and useful actions

<u>CAS-ViewAlert</u>: The alerts received in <u>May</u> and <u>December</u> 2024 are safety critical and complex National Patient Safety Alerts. Implementation should be co-ordinated by an executive lead and supported by clinical leaders in pharmacy, community pharmacy, GP practices, and clinical leaders in respiratory, pancreatology, pancreatic surgery, dietetics and cancer.

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

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

The supply disruption of Creon<sup>®</sup> capsules is due to limited availability of raw ingredients and manufacturing capacity constraints to produce volumes needed to meet demand. There are currently 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<sup>®</sup> 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<sup>®</sup> 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 1

Actions for clinicians and prescribers of PERT to be	Useful links:
completed by 31/01/2025 and to remain in place only	SPS: Shortage of Creon 10000 and 25000 gastro-resistant
until the supply issues have resolved (see Specialist	<u>capsules</u>
Pharmacy Service (SPS) Medicine Supply Tool for	
approximate resolution dates):	SPS: Prescribing and ordering available pancreatic enzyme
	replacement therapies
1. Clinicians should continue to follow the actions set out	
in the National Patient Safety Alert issued in May and	SPS: Find PERT alternatives and equivalences
December 2024.	
	Position Statement: Pert Shortage   Pancreatic Society of Great
2. NHS provider trust pharmacy procurement teams	Britain and Ireland
should ensure that where quantities greater than current	
demand are required, unlicensed imports should be	Creon supply update Cystic Fibrosis Trust
considered. 1	
	Guts UK - committed to fighting all digestive diseases
3. To ensure that patients are not left without PERT,	
Integrated Care Boards (ICBs) should:	Information about the supply of Creon, Nutrizym and Pancrex -
	Pancreatic Cancer UK
a. put in place a local mitigation plan for instances when	
patients are unable to obtain stock from their community	Several specialist importers have confirmed they can source
pharmacy or dispensing GP.	unlicensed PERT; please note there may be other companies that can
	also source supplies. The enzyme composition of unlicensed imports
b. cascade any local management plan to all community	may differ from UK licensed products; please refer to the datasheet
pharmacies and GP practices within the region, as well as	accompanying these products.
local trust pharmacy teams.	

<sup>&</sup>lt;sup>1</sup>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.

**Patients must not be left without any PERT.** This can lead to hypoglycaemia, severe bowel symptoms, poor absorption of other medications and weight loss.

## Actions for GP practices:

- Prescribe a maximum of one month's supply of PERT for all patients at a time.
- Issue repeat prescriptions ahead of patients need consider contacting patients taking PERT to advise them to order 2 weeks ahead of need to allow time for prescriptions to be filled and to share the patient information <u>link</u>.
- Ensure that prescriptions for PERT are generated on a separate script and print out or document the bar code token for the patient to take to the pharmacy. Please remember to send it as a separate prescription for patients without a pharmacy nomination (so that they can get this item dispensed at a separate pharmacy if required).
- If no licensed Creon<sup>®</sup> is available, consider switching to alternative licensed products (Nutrizym<sup>®</sup> 22 and Pancrex V<sup>®</sup>) using the dosage advice on the <u>SPS</u> website and page 3 below.
- Use 'advice and guidance' to contact the relevant specialist for advice if no licensed alternatives are available and if a patient's supply will run out in the next 10 days. The patient should be informed of this and if no alternative treatments are available the specialist will arrange for a one month supply from their Acute trust including unlicensed imports if needed.

### Actions for community pharmacy:

- Advise patients to order prescriptions 2 weeks ahead of need.
- Pharmacists presented with a repeat prescription for PERT should only supply the equivalent to **one month's supply** in accordance with the Serious Shortage Protocols <u>SSP060 and SSP061</u>.
- 1. Check if it is possible to order licensed products (by contacting AAH, Alliance and Phoenix wholesalers as availability may fluctuate).
- 2. Patients are generally advised to check stock in other pharmacies, and the PCN WhatsApp group can also be used for this purpose. However, with specialist medicines like Creon<sup>®</sup>, this may be more difficult.
- 3. If the patients' PERT preparation is showing as out of stock, please order to add onto the back-order list.
- 4. Currently, Vitaris supply Creon<sup>®</sup> to the wholesalers AAH, Alliance and Phoenix every 1-2 weeks. The customer helpline (0800 8086410) can advise on when and where the next deliveries to wholesalers are due.
- 5. If you cannot get the licensed product required, let the prescriber know if you can obtain alternative licensed products (Nutrizym<sup>®</sup> 22 and Pancrex V<sup>®</sup>) that can be dispensed on receipt of a new prescription and new dosage advice (see table on page 3 below and <u>SPS</u>).
- 6. If no licensed alternatives are available, ask the patient to contact their specialist team or the GP to contact via 'advice and guidance'. (If you order unlicensed PERT products, please ensure the ICB team are notified on hweicbhv.medicinesoptimisationteam@nhs.net to make them aware of new issues and which trust is out of stock).

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

#### Actions for Acute Trusts:

Where PERT is prescribed for indications other than cystic fibrosis, clinicians and prescribers should consider<sup>2</sup>:

- prescribing a proton pump inhibitor or H2 receptor antagonist short term to reduce acid degradation of the PERT and to optimise efficacy<sup>2</sup>
- o if a dose reduction may be suitable for patients based on severity of symptoms<sup>2</sup>
- o 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<sup>2</sup>
- prescribing medication to manage symptom control<sup>2</sup>

Inform specialists they may be contacted by patients directly, or by a GP practice using 'advice and guidance' including people without a specialist team for advice regarding alternatives. If a licensed product is unavailable from community pharmacy, the specialist team will arrange for a supply from their Acute Trust.

Dose equivalence table to calculate the new correct dosing regime

Or see SPS website: Find PERT alternatives and equivalences

Creon®	Equivalent	Equivalent	Equivalent	Equivalent	Equivalent	Pancrex <sup>®</sup> V
25 <b>,000</b>	in Nutrizym <sup>®</sup>	in Creon <sup>®</sup>	in Pancrex®	in Pancrex®	in Creon <sup>®</sup>	powder*
Dose	22	10,000	340mg	125mg	Micro*	
			(8,000 units	(2,950 units		
			lipase)	lipase)		
1 x Creon	1 x Nutrizym	3 x Creon	3 x Pancrex	8 x Pancrex	5 scoops	½ x 2.5ml
25 <b>,000</b>	22	10,000	8,000	2,950	Creon Micro	spoon
2 x Creon	2 x Nutrizym	5 x Creon	6 x Pancrex	16 x Pancrex	10 scoops	1 x 2.5ml
25 <b>,000</b>	22	10,000	8,000	2,950	Creon Micro	spoon
3 x Creon	3 x Nutrizym	8 x Creon	9 x Pancrex	24 x Pancrex	15 scoops	11/2 x 2.5ml
25 <b>,000</b>	22	10,000	8,000	2,950	Creon Micro	spoon
4 x Creon	4 x Nutrizym	10 x Creon	12 x Pancrex	32 x Pancrex	20 scoops	2 x 2.5ml
25 <b>,000</b>	22	10,000	8,000	2,950	Creon Micro	spoon
5 x Creon	5 x Nutrizym	13 x Creon	15 x Pancrex	40 x Pancrex	25 scoops	21/2 x 2.5ml
25 <b>,000</b>	22	10,000	8,000	2,950	Creon Micro	spoon
6 x Creon	6 x Nutrizym	15 x Creon	18 x Pancrex	48 x Pancrex	30 scoops	3 x 2.5ml
25 <b>,000</b>	22	10,000	8,000	2,95 <b>0</b>	Creon Micro	spoon

This table shows how each product compares to others (2).

Please check the storage recommendations on the label

– Some products may need refrigerating

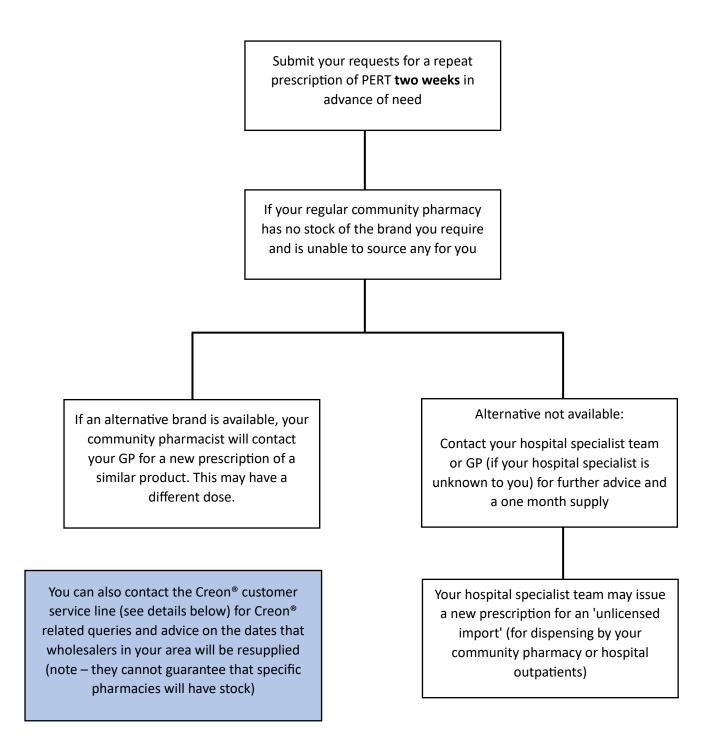
#### Advice for special patient populations

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. The Neonatal & Paediatric Pharmacy Group has recently published their own <u>position statement</u> on the shortage of PERT. It aims to provide practical advice on using alternative products, dosing equivalences, and prescribing guidance.

<sup>&</sup>lt;sup>2</sup> For advice on the use of reduced doses, optimisation of doses, and symptom control, please refer to the clinical advice in this <u>position statement</u>, endorsed by a number of professional bodies. Please note that medication prescribed for symptom control will not treat malabsorption and should not be considered as alternative to PERT.

# Pancreatic Enzyme Replacement Therapy (PERT) Patient Flow Chart Your medication - Herts and West Essex ICS

PERT is prescribed 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. You may have been advised how to adjust your dose according to your symptoms and if problems with digestion or weight loss occur.



We are working closely with our hospitals to regularly monitor their stock levels.

Creon<sup>®</sup> customer service line details:

Vitaris UK has initiated a free Creon<sup>®</sup> customer service line. The Creon<sup>®</sup> customer service line can be reached via 0800 8086410. Operators will respond from UK and handle enquiries in real time. The service will be active from Monday to Friday from 9:00 am to 5:00 pm

Useful links:

Position Statement: Pert Shortage | Pancreatic Society of Great Britain and Ireland

Creon supply update Cystic Fibrosis Trust

Guts UK - committed to fighting all digestive diseases

Information about the supply of Creon, Nutrizym and Pancrex - Pancreatic Cancer UK