

Norfolk and Waveney ICB: National Patient Safety Alert – Shortage of Pancreatic enzyme replacement therapy (PERT)

Background

In December 2024, a <u>National Patient Safety Alert (NPSA)</u> was issued in relation to the ongoing shortages of Pancreatic Enzyme Replacement Therapy (PERT). This alert reinforced previous information issued in <u>May 2024</u>.

There are currently limited supplies of the following pancreatic enzyme replacement therapies:

- Creon[®] 10000, Creon[®] 25000 capsules and Creon[®] Micro Pancreatin 60.12mg gastroresistant granules- available but in limited, capped quantities until anticipated re-supply January 2026. To help support demand, Creon[®] can now only be ordered via Alliance Healthcare UK wholesaler.
 - due to limited availability of the active pharmaceutical ingredients and manufacturing constraints to produce the volumes required to meet demand.
- Nutrizym[®] 22 capsules intermittent availability but not fully able to support an increase in demand.
- Pancrex V[®] 125mg capsules, Pancrex V[®] oral powder, Pancrex V[®] capsules currently unavailable. Anticipated resupply date of 125mg capsules Jan 2025, oral powder May 2025 and capsules June 2025.

In Norfolk and Waveney ICB, we currently have approximately 130 patients with cystic fibrosis (CF) and 2250 non-CF patients prescribed PERT.

General advice for clinician and prescribers in Primary Care:

- Prescribe a **maximum of one month's supply** of PERT for **all patients**. Pharmacies have been instructed via the alert to only supply the equivalent of one month's supply.
- Allow patients to **request a new prescription up to 14 days in advance** of the prescription due date. This will provide time for the pharmacy to source supplies if the drugs are out of stock. Do not post-date prescriptions, use the pharmacy text box to provide an explanation for the early prescription.
- Continue to prescribe licensed products where possible. Stock is still available although supply is disrupted. Unlicensed products should only be prescribed where pharmacies have not been able to obtain a licensed product through the usual wholesaler. NWICB have secured agreement from Oxford Pharmacy Store for the procurement of Pangrol[®]. This is an alternative unlicensed brand to Creon[®].
- Where possible avoid prescribing multiple brands / strengths to total a month's supply as this leads to further pressure on supply chains.
- PERT products should be prescribed on a separate prescription. This is to allow patients to obtain from a different pharmacy if required.
- Creon[®] 10000 capsules should only be prescribed for patients unable to take Creon[®] 25000 capsules e.g. children. If patients are prescribed Creon[®] 10000 due to swallowing difficulties consider switching to Creon[®] 25000 which can be opened and the contents

mixed with soft acidic food (e.g. apple sauce, yoghurt). The granules must not be chewed or mixed with hot food or drink.

- Creon[®] Micro Pancreatin 62.5mg capsules are prioritised for children and patients with dysphagia who are unable to open the Creon[®] 25000 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 with a medication administered via an enteral feeding tube. Generally, it should not be given orally as it may reduce the enzyme effectiveness and could cause harm to the oral mucosa.
- The Specialist Pharmacy Service (SPS) has developed a <u>conversion tool</u> to help identify equivalent and alternative products for UK <u>licensed</u> PERT products.

Advice for patients with non-CF indications

Where PERT is prescribed for indications **other** than cystic fibrosis **consider**:

- prescribing a Proton Pump Inhibitor (PPI) or H2 antagonist to optimise efficacy by reducing acid degradation. This is for symptom control only and will not treat malabsorption and should not be considered as an alternative to PERT.
- $\circ~$ a dose reduction / stopping PERT \underline{may} be appropriate in some patients based on severity of symptoms.
- \circ 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 symptoms should be investigated.
- prescribing medication to manage symptoms, for example antispasmodics or anti-diarrhoeals.
- referral to a specialist for advice on alternative treatments if the above options are unsuitable.

Advice for special patient populations

- Patients with Cystic Fibrosis must not be left without any PERT. This could lead to hypoglycaemia, severe bowel symptoms, reduced absorption of other medications and weight loss.
- For paediatric, neonatal and cystic fibrosis patients, continue to liaise with the patient's 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.
- Patients with diabetes may be more at risk of life-threatening hypoglycaemia if they are not taking adequate PERT doses.
- For further advice please consult the position statement produced by prescribers from the 'Nutrition Interest Group of the Pancreatic Society of Great Britain and Ireland (NIGPS), Cystic Fibrosis Specialist Group and Gastroenterology Specialist Group and the British Dietetic Association'.

Prescribing advice for Primary Care

• Licensed products should be prescribed where possible as stock is still available although supply is disrupted. Unlicensed products should only be prescribed where the pharmacy cannot obtain a licensed product through their usual wholesalers **and** the patient has less than 14 days' worth of medication left. Creon[®] is only available via Alliance Healthcare UK wholesaler.

Prescribing an unlicensed or imported PERT products including Pangrol®

- NWICB has secured procurement of unlicensed and imported Pangrol[®] via Oxford Pharmacy Store (OPS). This is an alternative brand to Creon[®] and is directly equivalent in strength. It is available in pack sizes of 200 capsules as either 10,000 or 25,000 strength. The lead time for delivery of Pangrol[®] to pharmacy is usually 1-2 business days.
- Liaise with the community pharmacy where an imported PERT product is required. Some pharmacies may source alternative imported products so it is important to establish what the pharmacy can supply to ensure the prescription is correctly written.
- Some unlicensed PERT products are mapped on the NHS Dictionary of Medicines and Devices (DM+D). These can be sent via EPS
- Where the unlicensed import PERT product is not mapped on DM+D, it must be issued on a **paper FP10 prescription.**
- Licensed products should continue to be prescribed via EPS.
- Patients must be informed of the rationale for the use of an unlicensed imported product. Justification for doing so must be documented in the patient's medical records.

Figure 1: Prescriptions for unlicensed / imported PERT products (including Pangrol®) must contain the following information:

- Name of medication including strength and formulation (imported)
- o Special order
- \circ $\;$ Dosage instructions for the patient
- Quantity
- Dispensing practices prescribing unlicensed / imported PERT should follow the guidance below.

SystmOne practices prescribing Pangrol®

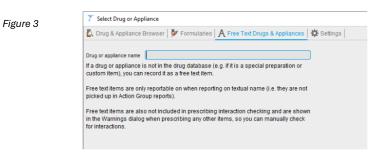
- Pangrol[®] can be searched for via the NHS Dictionary of Medicines and Devices (DM+D) database.
- Ensure the details in figure 1 are correctly endorsed on the prescription and issue via EPS.

Figure 2	Medication start Thu 13 Feb 2025	ngrol 25,000 capsules (Imported) [cost warning]	
	Script type O NHS Issue	Private Issue O Instalment Dispensed Issue	
	Dose use as directed with me	eals definition of the second definition of th	imes & Doses
	Total quantity Number 200 Packs Free Text	capsule	
	Script notes Special order	Presets	
	Administrative notes	Preset	s
	Issue duration 28 Days	End date 13 Mar 2025 💌 🎇 📓	

SystmOne practices prescribing other unlicensed / imported PERT products

• Only some unlicensed import PERT products are mapped via the DM+D database. Where listed, these can be sent via EPS.

• Imported PERT product which are not all mapped via the DM+D database will need to be free typed into the 'Free Text Drugs & Appliances' box when prescribing, ensuring it is endorsed with 'Special Order' (see figure 1).



EMIS practices

• Preparations need to be added using the 'add local mixture' as shown below:

	-	dd End Resulte	Generic / Trade Switch	y - 🚺 Drug Information 📧 Medication Review Lo	ST Matures 🛞 My Record -	
			HOUSE, Micky (Hr)		Bern 23-Jun-196 EMIS No. 50000	
Figure 4		Active V P	Name	Local Mixtures	×	Suppler
			Dosige	Mature Name / Constituent	Amount	
	*		Quantity x	i trigo		
		Drug / Dosaç	Rx Types Acute			
	-	A Co-codamol 100 tablet	Authorising Clinician LECKENBY, Sarah (C	2		
	data.	8 Enzalutamide				rigtion Information
	2	C Soprobec 10 puffs twice a becometason	Warnings Drug Information Current			Onican
	rd (No shar		[X] Adverse reaction to amoxicilin Adverse reaction to penicilins Adverse reaction to penicilins			08:41:00 JAYASWAL, Animesh (Dr) 09:24:00 SAUNDERS, Stuart H (Dr) 19:25:00 SAUNDERS, Stuart H (Dr)
	Mv Reco	E Aspirin 75mg F CD Bupreno Directed, Rem	Allergy to banana Allergy to peanuts Allergy to penicilin	Add	OK Cancel	
	View -	Alergies [X] Ar	Penicilin adverse reaction Warfarin allergy		23-Aug-202 04-Dec-2020	

Then choose 'add' in the local mixture box.

Click add drug, then choose local mixture

- The product will need to be identified from the lists of drugs from the multilex. Ensure all details from figure 1 are endorsed on the prescription.
- The prescription must be generated as a paper FP10 prescription.

Constituent	Amount	Inclu
Constituent		
Creon 25000 gastro-resistant capsules (Viatris UK Healthcare Ltd	i)	1
Pancrex V 125mg capsules (Essential Pharma Ltd)		1

Advice for community pharmacies and dispensaries

Community pharmacies and GP dispensers are free to order unlicensed or imported stock from an alternative route. Following the National Patient Safety Alert (NPSA) <u>NatPSA/2024/013/DHSC</u> NWICB have secured an alternative route for procurement of stock to supply patients who are unable to obtain licensed PERT products.

General advice

Figure 5

- Reassure patients that supplies of pancreatic enzymes are continuing and that Creon[®] and Nutrizym[®] products have not been discontinued.
- Please continue to dispense licensed products where available. Creon[®] is now only available via Alliance Healthcare UK.

- Patients have been advised to request prescriptions for their PERT up-to 14 days before it is due to allow time to source stock.
- Prescribers have been advised to only issue a maximum one month's PERT as per the most recent alert.
- Prescribers have been asked to prescribe PERT on separate prescriptions.
- **Do NOT** advise patients to obtain their prescription from a hospital pharmacy.
 - An exception to this is if **ALL** other attempts to obtain a product from the usual routes have been exhausted **AND** the patient has cystic fibrosis **AND** they have less than 7 days' supply remaining.
- The pharmacy should take all possible steps to obtain stock but where this is not possible, the patients should be directed to local pharmacy which is able to acquire stock
- Ensure the patient has been provided with the correct Patient Information leaflet.

Step 1 – dispensing licensed products

- **1.** Licensed products should be supplied where available in accordance with NWICB guidance.
- **2.** Viatris (Creon[®]) have advised they will now deliver stock to Alliance Healthcare wholesaler only with stock delivered three times a month.
- **3.** Both main suppliers in the UK of PERT have dedicated customer support lines to help identify where recent deliveries have been made:
 - Viatris (Creon[®]) 0800 8086410 (for patients and pharmacies).
 - Zentiva (Nutrizym[®]) 08448 793188 (for pharmacies) and 0800 902408 (for patients.
- 4. If the prescribed licensed PERT is showing as out of stock from your usual wholesaler and the patient has adequate stock (more than 14 days), please order to add onto the backorder list.
- 5. If the patient asks to try a different pharmacy, return the prescription to the spine and give a printed token to the patient.
- 6. Pharmacies presented with a valid prescription for licensed Creon[®] 10000 capsules or Creon[®] 25000 capsules should only supply the equivalent to one month's supply in accordance with the <u>Serious Shortage Protocol (SSP) 060 and SSP061</u> and endorse as directed by the SSP.

Step 2 – dispensing unlicensed products

- Liaise with the patient and prescribers where an unlicensed important product is required.
- If the product is mapped on NHS Dictionary of Medicines and Devices (DM+D) it can be sent via EPS. If the product is not mapped on DM+D a paper FP10 must be issued and state it is an 'Imported' or 'Special Order' product.

Incorrectly written EPS prescription for unlicensed Creon [®]	Correctly written prescription for unlicensed Creon [®]		
Prescribed Medication DISPENSING TOKEN Creon 250000 gastro-resistant capsules Take 1-2 capsules with meals 200 capsules Please supply imported product	Prescribed Medication DISPENSING TOKEN Creon 25000 gastro-resistant capsules (Imported) Take 1-2 capsules with meals 200 capsules		

Unlicensed/imported Pangrol®

- Norfolk and Waveney ICB preferred imported PERT product for prescribing is Pangrol[®]. A
 procurement agreement has been reached with Oxford Pharmacy Store (OPS) who can
 supply imported products within 1-2 business days. All community pharmacies are
 strongly encouraged to open an account with Oxford Pharmacy Store (OPS).
- You will need to open an account with OPS if you do not have an existing one. This can be completed by emailing <u>ops.orders@oxfordhealth.nhs.uk</u> (can take up to three days to setup). You will be required to supply the following details: Pharmacy name, address, email for remittance, ODS code.
- Stock can be ordered via email <u>ops.orders@oxfordhealth.nhs.uk</u>

Unlicensed / imported other PERT brands

- If you need to order an imported/ unlicensed PERT product other than Pangrol[®], the following specialist importers have confirmed they can source unlicensed PERT preparations if licensed products are unavailable (please note this may not be an exhaustive list)
 - Alium: can source unlicensed PANCREAZE®*
 - Durbin: can source unlicensed Zenpep^{®*}
 - Mawdsleys: can source unlicensed Creon[®]
 - Smartway: can source unlicensed Creon®
 - Target: can source unlicensed Creon[®], PANCREAZE[®]* and Zenpep[®]*

*PANCREAZE and Zenpep are available in different strengths, please check the strengths supplied. The enzyme composition on unlicensed imports may differ from UK licensed products; please refer to the corresponding Summary of Product Characteristics for specific product information.

Endorsing prescriptions for unlicensed/ imported PERT

- Unlicensed / imported prescriptions must be endorsed as a non-Part VIIIB special with the following information:
 - Amount dispensed over pack sized used
 - Invoice price per pack size from which the order was supplied less any discounts or rebate
 - Medicines and Healthcare products Regulatory Agency (MHRA) license number of the supplier or importer
 - Batch number of the product supplied
 - 'SP'

Advice for patients

In the UK, there currently is a shortage of a type of medicine called pancreatic enzyme replacement therapy (PERT) that some people need to help them digest food properly. The medicine is important for people whose pancreas doesn't make enough enzymes which help to breakdown food which the body uses for energy.

The shortage has happened because there have been problems manufacturing enough of this medicine and it has been hard to get the ingredients needed to produce it. To address the recent medication shortage, NHS Norfolk and Waveney Integrated Care Board (NWICB), has worked closely with community pharmacies, local hospitals and GP practices, to ensure patients continue receiving the necessary medications. 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 we're working to help everyone who needs PERT to get the medications they need in a timely manner.

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

- Place your prescription request with your GP surgery **14 days earlier** than you need it. This will 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 to a different pharmacy if your usual pharmacy is unable to obtain stock. Please be aware that if you are ordering your medication by an automatic system, the request may be rejected. If you're using the NHS app you should get notification if the prescription is rejected. If you're unsure, please contact your GP surgery to check.
- Some community pharmacies have online stock checking services which may be helpful so you can see if they are likely to have stock.
- Call the pharmacy ahead to confirm stock before making a special visit.
- If your pharmacy tells you your PERT is out of stock and you have more than 14 days' supply left, please ask them to order it anyway so the order is logged and will be filled when the next shipment of PERT arrives.
- Let your GP know if you are not able to get a prescription filled and have only 14 days' supply of PERT remaining. You may be prescribed a different PERT product which is equivalent to your usual product. Please talk to your GP surgery or community pharmacist about any queries or concerns you may have.
- You may be asked to go to a different pharmacy to receive your prescription. NWICB have a system in place to help patients access PERT medications.
- Both main suppliers in the UK of PERT have dedicated customer support lines to help identify where recent deliveries have been made:
 - o Viatris (Creon®) 0800 8086410
 - o Zentiva (Nutrizym®) 0800 902408

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.
- Do not stockpile medications. This makes supply issues worse for everybody. GP's have been told by the Department of Health to issue prescriptions for one month supply of PERT only. Pharmacies have been requested to only give a maximum of 28 days supply.
- Please do not ask for any old prescriptions you may have to be dispensed.
- Do not borrow or share medication with other patients or buy medications on the Internet.
- Please do not attend your local hospital pharmacy for dispensing of your PERT medication unless you have been told to do so by your GP.
- Remember to store your PERT medications below 25°. If the products get too hot, the enzymes are destroyed and will not work. In periods of prolonged extreme heat, store your PERT in a fridge.

Where to get further information?

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

The <u>Pancreatic Society of Great Britian</u> has produced some information which 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.

References:

National Patient Safety Alert: <u>Shortage of Pancreatic Enzyme Replacement Therapy (PERT)</u>. <u>NatPSA/2024/007/DHSC</u> May 2024

National Patient Safety Alert: <u>Shortage of Pancreatic Enzyme Replacement Therapy (PERT)</u>. <u>NatPSA/2024/013/DHSC</u> Dec 2024

Specialist Pharmacy Service: Find PERT alternatives and equivalences Jan 2025

Serious Shortage Protocol (SSP): SSP060 Creon® 10000 capsules. May 2024

Serious Shortage Protocol (SSP): SSP061 Creon® 25000 capsules. May 2024

National Position Statement: <u>Pancreatic enzyme replacement therapy (PERT) shortage = advice</u> for clinicians on the management of adults with pancreatic exocrine insufficiency. Nov 2024

Pangrol® 10000 V gastro-resistant capsules. Patient information leaflet. Jan 2017

Pangrol® 25000 Enteric-coated hard capsules. Patient information leaflet. June 2023

Acknowledgement to Derby and Derbyshire ICB PERT guidance. Dec 2025