

Shortage of Pancreatic Enzyme Replacement Therapy (PERT): Patient & Stock Management

There are ongoing supply limitations with Pancreatic Enzyme Replacement Therapy (PERT), in particular Creon® brand which is expected to last until 2026. Due to the impact of these issues and the associated timelines an NHS Grampian Expert Working Group (EWG) has been enacted in line with NHS Grampian Guidance for the management of medicine shortages.

Two National Patient Safety Alert (NPSA) and two Serious Shortage Protocols (SSPs) are in place to manage to ongoing supply issues with PERT

- NPSA
 - o NPSA: Shortage of PERT May 2024
 - o NPSA: Shortage of PERT December 2024
- Serious Shortage Protocols
 - o SSP: Creon® 10,000
 - o SSP: Creon® 25,000
 - SSP extension

Creon® is not out of stock, but is experiencing <u>limitations in supply</u> which are precipitating intermittent supplies to community pharmacy. To ensure there is as little disruption as possible to the supply network, all individuals involved in the management of this shortage are asked to comply with actions within NPSAs and SSPs to support stock management.

Actions for community pharmacy

- 1. Do not stockpile PERT.
- 2. Make supplies of PERT to patients of no more than the equivalent of one month's supply of medication (as per SSP). Where prescribed directions do not facilitate an understanding of dosing (i.e. as directed or when required) it is recommended that contact is made with the patient in advance to ascertain requirements. Prescriptions should be endorsed with quantities supplied and submitted for payment as per SSPs.
- 3. Continue to order supplies of PERT in line with prescription requirements and quantity limitations (see point 2).
- 4. Where supplies of PERT are unavailable, ensure wholesaler orders are resubmitted daily to ensure timely supplies of medication.
- 5. When appropriate, liaise with other local pharmacies to ensure timely supplies of PERT to patients (it is recommended that patients are not asked to contact other pharmacies by themselves as this can generate a significant amount of work for other pharmacies).
- 6. Where no suitable supplies can be procured, consideration should be given to ordering unlicensed Creon[®], noting the following points:
 - a. Unlicensed medicines should only be ordered where there is no stocks of licensed products available.

- b. Unlicensed medicines should only be ordered where there is an imminent need for medication. As supplies of licensed Creon[®] are intermittent attempts to order these should be made daily to secure licensed stock whenever possible.
- c. When ordering unlicensed stock, the quantity principles detailed in point 2 continue to apply.
- d. NHS Grampian specials process should be followed.

Actions for primary care

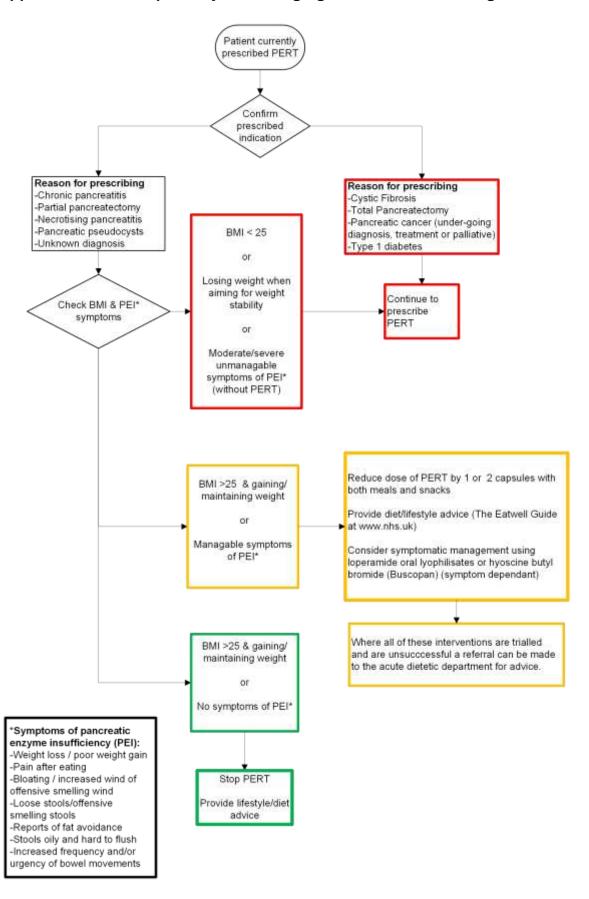
- 1. Please see Appendix 1 for flow chart to support with the management/review of patients prescribed PERT.
- 2. Do not switch Creon[®] patients to alternative PERT products or Creon[®] Micro, these products are reserved solely for patients who are unable to tolerate Creon[®].
- 3. See Appendix 2 for supporting patient information where advising patients/carers to undertake a reduction in PERT requirements alongside dietary/lifestyle advice.
- 4. Patients who are advised to reduce PERT, consider diet/lifestyle advice and symptomatic management should not be referred to the dietitian team without first trialling changes to dosing regimen and lifestyle/diet measures.
- 5. When referring to dietitian for further support please ensure all referrals are sent to gram.acutedietitianspert@nhs.scot and include the information listed below. Referrals without appropriate symptomatic management will be referred back to primary care. Please include the following details on any referral.
 - Patients name & CHI
 - Diagnosis
 - Interventions trialled (including duration of trial and patient response)

Further information

- NPSA: Creon: May 2024
- NPSA: Creon: December 2024
- SSP: Creon® 10,000
- SSP: Creon[®] 25,000
- Specialist Pharmacy Service: Shortage of Creon
- PSGBI Position Statement: Pert Shortage

This information has been produced in collaboration with the NHS Grampian PERT Expert Working Group (EWG).

Appendix 1: Clinical pathway for managing current PERT shortages



Appendix 2: Patient information sheet

Patient information: Supply issues with pancreatic enzyme replacement therapy (PERT)

What are the supply issues with Pancreatic Enzyme Replacement Therapy (PERT)? There are ongoing UK-wide supply issues PERT. These medicines are supplied under the brand names Creon[®], Nutrizym[®], and Pancrex[®]. Supply restrictions resulting in intermittent supplies of Creon[®] are anticipated to continue until early 2026.

Why are there supply issues with PERT?

The supply disruption of Creon® is due to limited availability of active pharmaceutical ingredients and manufacturing constraints to produce the volumes required to meet demand. This is a UK-wide issue.

Will I still receive supplies of my PERT medicine?

Where PERT supplies are required, your community pharmacy will continue to source and order stocks in line with your prescription requirements. Patients should not contact multiple pharmacies to obtain stocks as supply issues are UK wide.

In order to ensure supplies can be maintained for all patients, you will receive smaller quantities of PERT than you would usually receive (a maximum of one month's supply at a time). As a result you may have to collect your PERT prescriptions on a more regular basis. This is in line with Scottish Government recommendations and is to ensure that all patients requiring medication can receive a timely supply.

To support with the management of PERT stocks during this time your community pharmacy may ask you how much medicine you have at home and how much you use on a daily basis. This is to ensure they can ensure all patients receive appropriate and timely supplies of their PERT.

Can my GP help me with PERT supplies?

To support patients during this time, your GP practice will review your PERT requirements and provide you with advice regarding ongoing usage of PERT in line with your condition/requirements. This will be undertaken using advice and support from NHS Grampian clinical experts.

Your GP may advise you to reduce doses of PERT taken with meals and snacks.

Further advice regarding a healthy diet to support with minimising PERT requirements can be found at www.nhs.uk and searching 'The Eatwell Guide'.

Your GP practice cannot source PERT stocks for you.

Where can I get more information?

Further information and advice can be found on the Position statement and advice for patients from the Nutrition Interest Group of the Pancreatic Society of Great Britain and Ireland (NIGPS), Cystic Fibrosis Specialist Group and Gastroenterology Specialist Group, British Dietetic Association (accessed via https://www.psgbi.org/position-statement-pert-shortage/)