

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

SHORTAGE OF PANCREATIC ENZYME REPLACEMENT THERAPY (PERT) – PRIMARY CARE GUIDANCE

This guide has been compiled to support patients to source PERT during the ongoing shortage. This guide is intended to aid in the prescribing and dispensing process, ensuring patients receive PERT promptly based on availability and prioritised clinical need.

Background

PERT is indicated 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. Many patients adjust their dose according to symptom management, but all patients should be counselled to re-titrate the dose if problems with digestion or weight loss occur.

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

- Creon® 10,000 and 25,000 capsules are in limited supply until 2026.
- Pancrex V® and Nutrizym capsules® 22 capsules both remain available but are unable to support an increase in demand.
- Unlicensed imports like Pangrol®

The supply disruption of Creon® capsules is due to limited availability of active pharmaceutical ingredients and manufacturing constraints to produce the volumes required to meet demand. The supply disruption for Nutrizym® 22 capsules and Pancrex V® capsules has been caused by a manufacturing issue and increased demand because of the Creon® supply issue.

Recommended actions (as outline on NatPSA's)

- 1) Clinicians should:
 - A. Prescribe a maximum of one month's supply of PERT for all patients at a time.
 - B. Prioritise available Creon 10,000 capsules for patients unable to take Creon 25,000 capsules only.
 - C. Prioritise remaining stock of Nutrizym® 22 capsules and Pancrex V® capsules for patients unable to tolerate Creon capsules.
 - D. Where PERT is prescribed for indications other than cystic fibrosis, clinicians and prescribers should consider:
 - Prescribing a proton pump inhibitor or H2 receptor antagonist to optimise efficacy
 - if a dose reduction may be suitable for patients based on severity of symptoms
 - where symptoms remain despite a dose of $\geq 10,000$ 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
 - E. prescribe unlicensed imports of PERT only where licensed alternatives are unavailable, working with local pharmacy teams to ensure orders are placed within appropriate time frames

- F. Immediately refer patients to a specialist for advice on alternative treatments if above options are not suitable.
- 2) Pharmacists presented with repeat prescription for PERT should only supply the equivalent to one month's supply in accordance with [SSP060](#) and [SSP061](#).

Guidance on prescribing

- Prescribe PERT medication as a single item on a prescription – multiple items on the prescription restricts patients being able to try multiple pharmacies – This can create a delay when a new prescription needs to be issued.
- Please liaise with patients' pharmacy, to establish what preparation is available. Prescribe accordingly based on the license status of the preparation, ensuring the below requirements are met so that a special order can be dispensed correctly

Unlicensed preparations

There are a number of specialist importers that can source unlicensed PERT preparations.

Use the NHS Dictionary of Medicines and Devices (DM+D) database to select the correct unlicensed product but if it is not on the database then prescribers are encouraged to free type the name with '(Special Order)' included as part of the drug name field (see Figure 1)

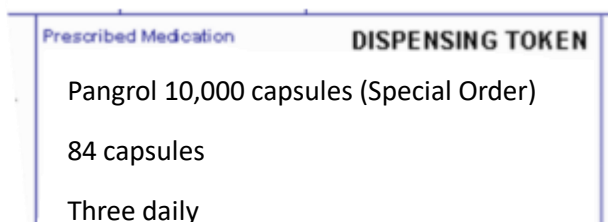


Figure 1: Example of correctly issued electronic prescription for a non-Part VIII special

If the product isn't on DM+D, the preparation needs to be added manually. For SystemOne practices, please utilise the 'Free Text' option rather than handwriting so there is a record of what you have given for the future and the prescription can be identified when running searches.

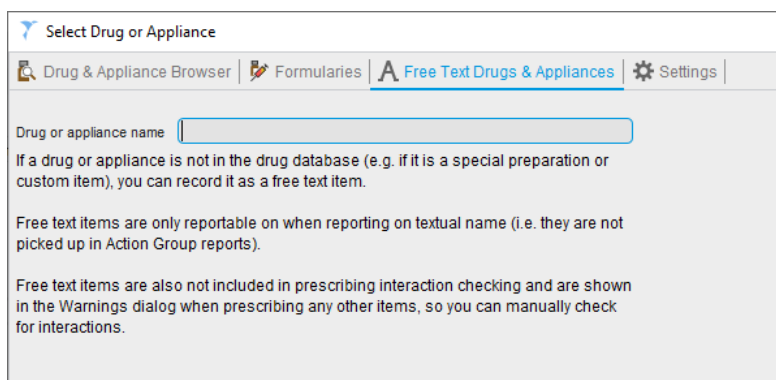
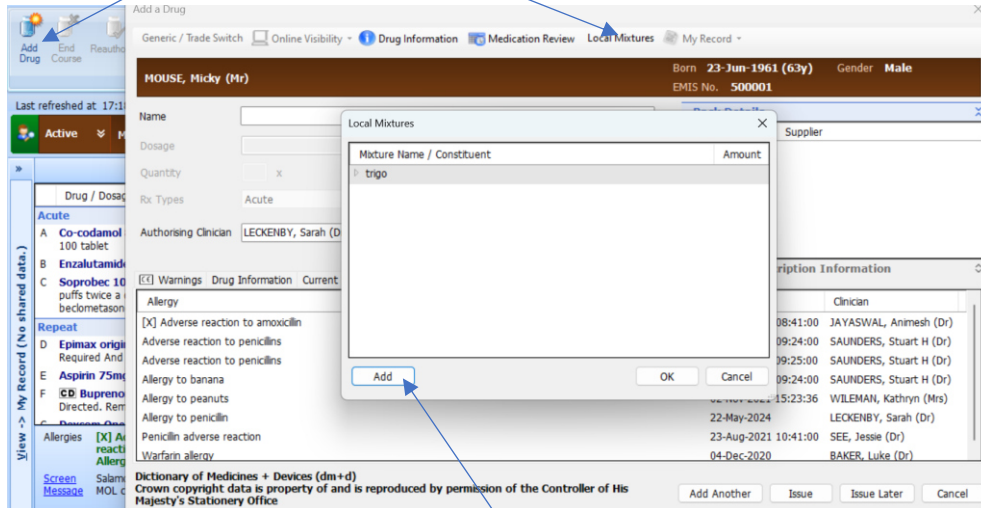


Figure 2 : SystemOne Free Text option for preparations not on DM+D

For EMIS Practices, preparations need to be added using the option 'add local mixture' as outlined below ;

To add a local Mixture on EMIS:

Click add drug, then choose local mixture



Then choose 'add' in the local mixture box.

You then need to identify the constituents which need to be actual drugs from the multilex

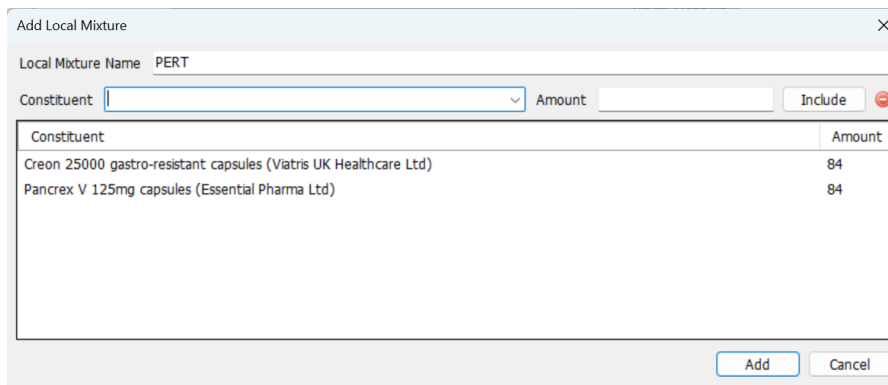


Figure 3 – Adding new local mixture on EMIS

Additional resources

Pancreatic Society Great Britain & Ireland (PSGBI)

This site has [two available resources](#) (position statements) with respect to the shortages.

The [health care professional resource](#) contains advice with clinical management as well as the differences in preparations available.

The [patients](#) resource contains advice on symptom control, dietary amendments and further information on ordering prescriptions in ample time.

Specialist Pharmacy Service (SPS)

This website require sign up to access, but provides a number of resources regularly updated.

[Medication supply tool](#) – Current availability of the different preparations

[Prescribing and ordering available pancreatic enzyme replacement therapies](#) – further information on the different preparations, and a link to the SPS mini tool which provides options for PERTs by matching a patient's current therapy against equivalent UK licensed products. It also states the enzymatic constituents by product and individual dose.

References:

SPS Medicine Supply Tool Prescribing and ordering available PERT therapies [Prescribing and ordering available pancreatic enzyme replacement therapies – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

NHS BSA Serious Shortage Protocol SSP061 [SSP061 Creon 25000 restriction FINAL 23052024 - Signed.pdf](#)

NHS BSA Serious Shortage Protocol SSP060 [SSP060 Creon 10000 restriction FINAL 23052024 - Signed.pdf](#)

[How prescriptions for unlicensed specials should be written - Community Pharmacy England](#)

National Patient Safety Alert PERT - <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103260>