



## PERT UPDATE JULY 2024

### PERT SHORTAGES

As you may be aware, over the last few months, we at Neuroendocrine Cancer UK have been working with charity partners to address the urgent need to resolve the current shortages of PERT.

At the end of May 2024, an alert was sent out across NHS organisations (see pages 3-4). The advice included a list of approved unlicensed products that could be prescribed if the usual supply was not available.



**National  
Patient  
Safety Alert**



Department  
of Health &  
Social Care



**NHS  
England**

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Shortage of Pancreatic enzyme replacement therapy (PERT)

*Please note: all products are FDA approved - the license refers to import regulations.*

In June 2024, an updated Position Statement (V3) was published by the Pancreatic Society of Great Britain & Ireland (PSGBI):

For the latest clinician and patient versions, visit:  
[www.psgbi.org/position-statement-pert-shortage/](http://www.psgbi.org/position-statement-pert-shortage/)  
or use the QR code provided here:



**Position Statement: PERT shortage – advice for adults with pancreatic exocrine insufficiency**  
Philipps M.E., McGerrey L.M., Watson K.L., Lavelle J.

**Position Statement: Pancreatic enzyme replacement therapy (PERT) shortage – advice for adults with pancreatic exocrine insufficiency**  
Philipps M.E., McGerrey L.M., Watson K.L., Lavelle J.

Issue date: 24<sup>th</sup> June 2024 (Version 3)


Please ensure you are reading the most up to date version, which is available on the Pancreatic Society of Great Britain and Ireland Website: <https://www.psgbi.org/position-statement-pert-shortage/>

We now share an update on developments, received today (Friday 12th July 2024), from the Senior Pharmacist, Medicine Supply Team, Medicines Directorate, Department of Health and Social Care:

- Creon 25,000: is moving into a much more stable position with stock made available each month to cover allocated supply. Deliveries will be released to wholesalers at intervals across the month. The Medicines Supply Team at the DHSC has asked Viatris to provide details of release dates which they hope to share as approximate replenishment dates are confirmed.
- Creon 10,000: the next delivery into the UK is w/c July 15th and will be made available within that week to most wholesalers, subsequent supply in August but the exact date is to be confirmed by the end of July.
- Viatris has had successful discussions with manufacturers to secure additional stock of Creon 25,000 which will be made available between August-October and will also supply additional stock of Creon 10,000 in place of a quantity of Creon 25,000 which will be made available in September.
- Regarding current supplies, Viatris has implemented weekly caps for community pharmacies to control the quantity of packs dispensed and is setting up a Creon call line for healthcare professionals (HCPs) and patients to provide details on which pharmacies have received stock – the Team at the DHSC are awaiting further details from the company on the communication plans for these actions.
- The Team is also working with the Specialist Pharmacy Service (SPS) on a public-facing page to include advice for HCPs on availability and prescribing during this period – they will share a link to this once live.

## Shortage of Pancreatic enzyme replacement therapy (PERT)

<b>Date of issue:</b>	24-May-24	<b>Reference no:</b>	NatPSA/2024/007/DHSC
This alert is for action by: All organisations involved in prescribing and dispensing pancreatic enzyme replacement therapy (PERT).			
This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in community pharmacy, GP practices and clinical leaders in pharmacy, dietetics, respiratory, hepatobiliary and cancer services.			

Explanation of identified safety issue:	Actions required 
<p><b>This alert supersedes the Medicine Supply Notification (MSN/2024/054) issued on the 9<sup>th</sup> May 2024.</b></p>	<p><b>Actions for clinicians and prescribers of PERT to be completed 10/06/2024</b></p>
<p>There are limited supplies of pancreatic enzyme replacement therapies (PERT).</p> <ul style="list-style-type: none"> <li>Creon® 10,000 and 25,000 capsules are in limited supply until 2026.</li> <li>Nutrizym® 22 capsules are out of stock until mid-August 2024.</li> <li>Pancrex V® capsules and powder remain available but are unable to support an increase in demand.</li> </ul> <p>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.</p> <p>The supply disruption for Nutrizym® 22 capsules has been caused by a manufacturing issue and increased demand because of the Creon® supply issue.</p> <p>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.</p> <p>Unlicensed imports of Creon® capsules and alternative brands of PERT may be sourced, lead times vary.</p> <p>Information relating to imports is available below and on the SPS Medicines Supply Tool which also details any changes to resupply dates, updates to this communication and an up-to-date supply overview.</p>	<p>To remain in place <u>only until the supply issues have resolved</u> (see SPS Medicine Supply Tool):</p> <ol style="list-style-type: none"> <li>1. Clinicians should:             <ol style="list-style-type: none"> <li>a. prescribe a maximum of one month's supply of PERT for all patients at a time.</li> <li>b. prioritise available Creon 10,000 capsules for patients unable to take Creon 25,000 capsules only. <sup>Note A</sup></li> <li>c. prioritise remaining stock of Nutrizym® 22 capsules for patients unable to tolerate Creon capsules.</li> <li>d. where PERT is prescribed for indications other than cystic fibrosis, clinicians and prescribers should consider:                 <ul style="list-style-type: none"> <li>• prescribing a proton pump inhibitor or H2 receptor antagonist to optimise efficacy <sup>Note B</sup></li> <li>• if a dose reduction may be suitable for patients based on severity of symptoms <sup>Note B</sup></li> <li>• 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>Note B</sup></li> <li>• prescribing medication to manage symptom control <sup>Note B</sup></li> </ul> </li> <li>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.</li> <li>f. immediately refer patients to a specialist for advice on alternative treatments if above options are not suitable.</li> </ol> </li> <li>2. Pharmacists presented with repeat prescription for PERT should only supply the equivalent to one month's supply in accordance with <a href="#">SSP060</a> and <a href="#">SSP061</a>.</li> </ol>

## Additional information:

### Clinical Information

Creon® gastro-resistant capsules and Nutrizym® 22 capsules are licensed for the treatment of pancreatic exocrine insufficiency. 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.

**Note A:** Supply of Creon 10,000 capsules should be reserved for patients unable to take Creon 25,000 capsules only. Where patients are prescribed Creon 10,000 due to swallowing difficulties, consider the suitability of prescribing Creon 25,000 capsules which may be opened and mixed (without crushing) with soft acidic food (e.g., apple sauce or yoghurt). It is very important granules are not chewed or mixed with hot food. Patients should be counselled on oral care, including rinsing the mouth after eating, and ensuring dentures are cleaned regularly as granules can get stuck in the gums and under dentures and cause ulceration.

**Note B:** For advice on the use of reduced doses, optimisation of doses, and symptom control, please refer to the clinical advice in this [position statement](#), 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.

**The following specialist importers have confirmed they can source unlicensed PERT preparations** (please note there may be other companies that can also source supplies):

**The enzyme composition of unlicensed imports may differ from UK licensed products; please refer to corresponding Summary of Product Characteristics for specific product information.**

- Alium (PANCREAZE® Delayed-Release Capsules)
- Durbin (Zenpep® Delayed-Release Capsules)
- Mawdsleys (Creon®)
- Smartway (Creon®)
- Target (Creon® PANCREAZE® Delayed-Release Capsules, Zenpep® Delayed-Release Capsules)

### References:

1. [SPC Creon gastro-resistant capsules](#)
2. [SPC Nutrizym gastro-resistant capsules](#)
3. [SPC Pancrex V](#)
4. [BNF: Pancreatin](#)
5. [UK Guidelines on the management of pancreatic exocrine insufficiency](#)
6. [Position Statement: PERT Shortage](#)
7. [SPS Medicine Supply Tool](#)
8. [NHS BSA Serious Shortage Protocols](#)

### Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Services; Medicines Shortage Response Group; NHS England; national clinical experts in Cystic Fibrosis, Pancreatology, Pancreatic Cancer, Gastroenterology and national patient safety team; Medicine and Healthcare products Regulatory Agency and the Devolved Governments

### Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to [CHT/2019/001](#) your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.

## PERT SURVEY

We would like to thank those of you who have already completed our PERT Survey—over 100 people so far. Whether you have had a supply issue or not, we would love to hear from you. You can take part [HERE](#).

If you are experiencing any difficulties with your PERT prescription, please feel free to download and print this document to share with your prescribing and/or dispensing teams.

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### Further resources and links

Neuroendocrine Cancer UK website:

[www.neuroendocrinecancer.org.uk](http://www.neuroendocrinecancer.org.uk)

Neuroendocrine Cancer UK YouTube:

[www.youtube.com/@neuroendocrinecanceruk](http://www.youtube.com/@neuroendocrinecanceruk)

Pancreatic Society of Great Britain & Ireland:

[www.psgbi.org/position-statement-pert-shortage/](http://www.psgbi.org/position-statement-pert-shortage/)

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We will continue to work with you, our community, our charity colleagues, and other stakeholders, including the DHSC and NHS, towards a sustainable solution.

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In the meantime, if you or a loved one needs support or information, please do get in touch.



Our helpline support team is here to assist you:  
Call us at **0800 434 6476**, available Tuesday to  
Thursday from 10am to 4pm, or use our  
**Contact Us** form.

