



Royal Surrey
NHS Foundation Trust

Pancreatic enzyme replacement therapy national shortage

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Declaration of interests – Honoraria received for teaching from Abbott, Viatrix, Nutricia Clinical Care and Nordmark Pharma.

Pancreatic enzyme replacement therapy (PERT)

- Essential medication for patients with pancreatic exocrine insufficiency (PEI)
- PEI is a failure of the pancreas to secrete sufficient enzymes to allow normal digestion
- Untreated PEI results in malnutrition, diarrhoea, faecal urgency and incontinence, bloating, reflux, colicky abdominal pain, micronutrient deficiency, erratic blood glucose control, fatigue and reduced performance status.
- The osmotic diarrhoea caused by untreated PEI could influence the absorption of other medications
- Fat malabsorption due to untreated PEI can impact Vitamin K uptake (caution for patients on anti-coagulation)



The impact on the patient

- Insufficient PERT will cause malnutrition, uncontrolled diabetes, significant abdominal symptoms and poor quality of life
 - Less likely to tolerate chemotherapy
 - Declining nutritional status prior to major surgery
 - Unable to work
 - Potentially life-threatening hypoglycemia
 - Long term impact of hyperglycaemia
 - Impact on psychological, social and financial status
 - Poor absorption of other medications.
- **There is no alternative**





'I had to do an 80-mile trip': the stress caused by UK drug shortages

Vital cystic fibrosis drug and HRT among medications people have struggled to find, as shortages become 'new normal' in UK

Simon Bell, a 43-year-old data analyst from Tyne and Wear, has cystic fibrosis and requires medication that allows him to digest food. "For people with cystic fibrosis, the part of our pancreas which releases enzymes and allows us to digest food doesn't work, so we have to take these tablets, which does the job of what's missing from our pancreas," he says.

Since the outbreak of the coronavirus pandemic, Bell says he has been experiencing shortages of Creon 25000, the drug he takes, and once was unable to get his medication for more than three months.

Bell decided he had no choice but to stockpile the medication when he could get it, as the effects of going without the drug are much graver than taking a lower dose.



BBC/PIERS HOPKIRK

The journey so far.....



Medicine Supply Notification

MSN/2024/089

Creon® Micro Pancreatin 60.12mg gastro-resistant granules
 Tier 3 – high impact*
 Date of issue: 23/08/2024
 Link: [Medicines Supply Tool](#)

Summary

- Creon® Micro Pancreatin 60.12mg gastro-resistant granules are in limited supply until late September 2024.

Re: Imp
 As you have decided to note that...



The situation now

- Ongoing shortages predicted into 2026
 - Supplies released to wholesalers 3 x month
 - Supplies only 90-95% of normal demand (Creon 25,000 only)
 - Prioritise Creon[®] Micro for infants and those with dysphagia who are unable to open the capsules
 - Prioritise Creon[®] 10,000 and Pancrex[®] capsules (5,000 and 8,000) for children & those unable to swallow large capsules
 - Prioritise Nutrizym 22[®] for those unable to tolerate Creon[®]
 - Prioritise Pancrex[®] powder for tube fed patients
 - **Import Creon[®] to meet deficit in demand**
 - **Import alternative PERT products for those unable to tolerate Creon[®]**





Position Statement: Pancreatic enzyme replacement therapy (PERT) shortage – advice for the management of adults with pancreatic exocrine insufficiency

Phillips M.E^{1,3}, McGeeney L.M¹, Watson K-L², Lowdon J².



Step wise advice

Phase 1: Patient with supplies

Phase 2: Patient with limited supplies

Phase 3: Patient with insufficient supplies and symptomatic

Phase 4: No supplies



Disease specific advice

- People with Cystic Fibrosis (CF) will be under the care of a CF centre – please contact them for advice, *Cystic Fibrosis Trust*.
- People with Pancreatic Cancer: *Pancreatic Cancer UK, Pancreatic Cancer Action*
- People with Neuroendocrine tumours: *Neuroendocrine Cancer UK*
- People with other GI diseases causing PEI (including chronic pancreatitis, post severe acute pancreatitis, benign pancreatic resection, ampullary/ duodenal/ cholangio cancers, gastrectomy, oesophagectomy): *GUTS UK*



Phase 1: patient with supplies

- Altering product supply to meet patient's needs
- Do not stockpile medicines
- Check expiry dates and ensure proper stock rotation
- Put the next prescription request in as soon as one is dispensed
- Ensure dose is spread throughout meals and swallowed with a cold drink to optimise efficacy

For patients who do not have cystic fibrosis

- Add in a PPI / loperamide as first line in those who have ongoing symptoms before a dose increase
- In patients who are on high doses, nutritionally stable and with minimal abdominal symptoms try and reduce by 1 capsule with their meals



Advice to GPs & Community Pharmacists

- Prescribe one month's worth at a time
- Ensure those who pay for prescriptions are aware of pre-payment certificates
- Availability updates via Specialist pharmacy Service:
<https://www.sps.nhs.uk/articles/prescribing-and-ordering-available-pancreatic-enzyme-replacement-therapies/>
- Allow next prescription to be placed as soon as previous one dispensed



Phase 2: Limited supplies

- Ensure optimal use of existing product: timing, storage as per Phase 1
- People with CF should contact their specialist centre
- We are aiming to make their supplies last longer
- Monitor for weight loss, altered glycaemic control, worsening abdominal symptoms.

For people who do not have CF

- Reduce dose by 1 capsule with meals
- If nutritionally stable encourage low fat snacks which do not need PERT
- If gastrically fed, consider giving PERT via PEG/NG at mealtimes in those eating alongside feed (this does not work with jejunal feeds).
- Use peptide oral nutritional supplements (ONS) in place of polymeric to reduce need for PERT



Phase 2: Advice to GP's and Community Pharmacists

- Prescribe imported medication (unlicenced)
- In severe cases rescue prescriptions from hospitals if patients run out altogether (if patients are under the care of a hospital team)
- GP prescriptions are not usually valid at Hospital Pharmacies – local arrangements are in place in some areas – contact your ICB
- Please ensure repeat prescription requests are not rejected if placed within 4 weeks of the last issue
- Keep prescriptions on the spine if possible, to allow patients to move between pharmacies.
- Viatris have issued a help line for pharmacy's and patients to identify areas with stock: 0800 8086410













Formulary additions

Sussex Partner Formulary **Sussex Health&Care** **NHS Sussex**

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Shared Care Guidance Not Recommended Items Latest APC Summary Discontinuations Contact us

- Pancreatin 
- Pancreatin (unlicensed) 
 - Pancreaze (Alium) 10500 Capsules 
 - Pancreaze (Alium) 21000 Capsules 
 - Pancreaze (Target) 10500 Capsules 
 - Pancreaze (Target) 21000 Capsules 
 - Zenpep (Durbin) 10000 Capsules 
 - Zenpep (Durbin) 25000 Capsules 
 - Zenpep (Target) 1000 Capsules 


Guildford And Waverley Joint Formulary
Guildford & Waverley ICP
Royal Surrey NHS Foundation Trust

Pancreaze Delayed-Release capsules


   

Formulary



Indication: Pancreatic enzyme replacement therapy

Added August 24 in line with NPSA alert on shortages

 [NatPSA/2024/007/DHSC Shortage of Pancreatic enzyme replacement therapy_\(PERT\)](#)

Other considerations

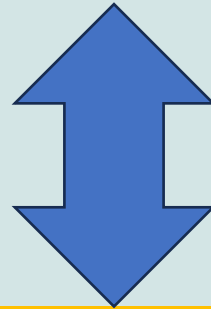
- Vitamin K – patients on anti-coagulation should be flagged to their GP as may need more regular monitoring
- Malabsorption is osmotic diarrhoea – may impact absorption of other medication – seizure medication, anti-coagulation, anti-hypertensives, thyroxine, oral contraceptive pills
- Consider increased monitoring of people on these medications
- Consider a secondary form of contraception at this time
- Allow increased prescription of blood glucose monitoring equipment – blood sugars will be more erratic and difficult to predict
- Loperamide may help – consider regular dosing – such as 2mg at night or BD if insufficient (not after each bowel motion) (Not for CF)



Current phase

“You’ll have to do without”

Phase 2



Phase 3



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Phase 3: symptomatic

Insufficient supply with abdominal symptoms / malnutrition

- People with CF – contact their local specialist centre ASAP
- For total pancreatectomy / difficult to control diabetes – urgent rescue prescription from local hospital (via HPB or diabetes team)
- If there is an ICB agreement with the local hospital for rescue prescriptions – implement this ASAP.
- Use advice and guidance / urgent referral routes for patients not known to hospital teams where the patient is not known to a Consultant team.
- Remember Dietitians and CNSs cannot arrange prescriptions for patients not under the care of a hospital consultant



Advice to GPs & Community Pharmacists

- **Imports are essential**
 - Step by step process in MSN and on SPS website on how to do this.
- **Ensure** patients on insulin have continuous glucose monitoring devices and know how to use the “low reading” alert
- **BE AWARE** – risk of falls in frail patients with faecal urgency

In those who do not have cystic fibrosis

- Use loperamide to try and control diarrhoea
- Consider additional medication to help control gastro-intestinal symptoms – i.e. Buscopan



PERT and absorption

- PERT plays a key role in absorbing
 - Starchy carbohydrates
 - Protein
 - Long chain triglyceride and some medium chain triglyceride
- Nutritional supplements that contain the following may be absorbed without PERT
 - Glucose
 - Peptides / amino acids
 - Medium chain triglycerides
- The stomach, small bowel and colon also play a role, especially with protein and starchy carbohydrates – so people who have pancreatic disease and have had a partial / total gastrectomy / colectomy / small bowel resection do not have as many compensatory mechanisms, and are likely to have more severe symptoms



Phase 3

Dietary measures

- Lower fat diet (half normal fat content)
- Reduce very high fibre foods (<40g fibre per day)
- Prioritise PERT with larger more nutritious meals
- If it is necessary to further reduce doses do so with small snacks first / reduce one capsule per meal rather than skipping whole meal doses
- If no diabetes – use sugary foods to keep energy levels up
- If losing weight / nutritional compromise –add in peptide ONS



Phase 3

Nutritional support without PERT

- Peptide formulae is first line (Vital 1.5kcal, Survimed OPD 1.5kcal, Peptisip Energy HP)
- Fat free ONS if patients are weight stable and do not have diabetes – sip slowly, be aware may not absorb protein / CHO optimally
- MCT products alongside fat free ONS (Liquigen[®] / MCT Oil)
- Peptide protein supplements (ProSource Jelly[®] / ProSource Plus[®])
- If still malabsorbing / nutritionally compromised – Emsogen[®]

(Note Elemental 028 Extra[®] is only 35% MCT and not suitable)



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Shared Care Guidance Not Recommended Items Latest APC Summary Discontinuations Contact us



Shortage of Pancreatic enzyme replacement therapy (PERT) NHS Sussex response

Vital 1.5 ✓

ACBS BRAND NICE emc+

Emsogen ✓

NICE emc+

Peptamen ✓

NICE emc+

Peptisip ✓

NICE emc+

Survimed ✓

NICE emc+

Liquigen ✓

NICE emc+

MCT ✓

NICE emc+



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Phase 4

If no supplies at all:

- Losing weight
- Uncontrollable bowel symptoms
- Drug absorption – consider seizure medications / anticoagulation / OCP
- Move to peptide based ONS in place of food (sip slowly)
- Continue with vegetable / sugar-based snacks (caution – Diabetes)
- Add sugar-based coffee / milkshake syrups to increase flavour range
- Reassure patient this will be short term
- Monitor blood glucose carefully and liaise with diabetes team if needed
- In a minority of cases enteral feeding may be required



Imported medications: considerations



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 April 2024
EMA/91157/2024

**Shortage of Creon (pancrelipase/pancreas powder)
hard capsules for oral use (10,000, 25,000 and 35,000 units)**

Google Translate

"Yesterday I received from my pharmacist two jars of "Kreon für Kinder" 60.12. Not capsules but loose granules with a tiny measuring scoop – how do I use these?"



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Imported Creon



Australia



Qatar



Canada



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What about those who can't tolerate Creon?



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Pancreaze (VIVUS)



pancreaze®
(pancrelipase) DELAYED-RELEASE CAPSULES



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| Preparation | Pack size | Description | Amylase | Protease | Lipase |
|--|-----------|---|---------|----------|--------|
| PANCREAZE Delayed- release capsules (Made by Vivus) (Imported by Alium) | 100 | Light orange body, clear cap VIVUS MT2 | 15,200 | 8,800 | 2,600 |
| | 100 | Yellow opaque body, clear cap, VIVUS and MT4 | 24,600 | 14,200 | 4,200 |
| | 100 | Flesh opaque body and clear cap VIVUS and MT10 | 61500 | 35500 | 10,500 |
| | 100 | Flesh opaque body and clear cap VIVUS and MT16 | 98,400 | 56,800 | 16,800 |
| | 100 | White opaque body and cap, VIVUS and MT20 | 83,900 | 54,700 | 21,000 |
| | 50 | Iron grey opaque body and white opaque cap VIVUS and MT37 | 149,900 | 87,300 | 37,000 |



Zenpep (Nestle)



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<https://www.zenpep.com/>

| Preparation | Pack size | Description | Amylase | Protease | Lipase |
|--------------------------|-----------|---|---------|----------|--------|
| Zenpep | 100 | White body and cap APTALIS 3 (in red) | 14,000 | 10,000 | 3,000 |
| Delayed-release capsules | 100 | White body and cap APTALIS 5 (in blue) | 24,000 | 17,000 | 5,000 |
| | 100 | White body and yellow cap APTALIS 10 | 42,000 | 32,000 | 10,000 |
| (Made by Nestle) | 100 | White body and red cap APTALIS 15 | 63,000 | 47,000 | 15,000 |
| (imported by Durbin) | 100 | White body and green cap APTALIS 20 | 84,000 | 63,000 | 20,000 |
| | 100 | White body and blue cap APTALIS 25 | 105,000 | 79,000 | 25,000 |
| | 100 | White body and orange cap APTALIS 40 | 168,000 | 126,000 | 40,000 |
| | 100 | White body and blue cap with 2 black stripes APTALIS 60 | 252,000 | 189,600 | 60,000 |

Viokace (Nestle)



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| Preparation | Pack size | Description | Amylase | Protease | Lipase |
|--------------------|-----------|--|---------|----------|--------|
| Viokace Tablets | 100 | Tablets – tan, round, biconvex VIO9111 on one side and 9111 on the other | 39,150 | 39,150 | 10,440 |
| (Target) | 100 | Tan, oval, biconvex with V16 on one side and 9116 on the other | 78,300 | 78,300 | 20,880 |

Warning: Contains lactose

https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022542s0001bl.pdf



Be careful.....



MICRAZYM 10,000 Ph.Euro.U
50 Capsules – Super Strength
Pancreatic Digestive Enzymes
Supplement – Amylase,
Protease and Lipase in Our
Unique Two-Stage Protect &
Precision delivery Micro-
Pellet System

Brand: AVVA PHARMACEUTICALS

4.4 ★★★★★ 305 ratings

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Amazon's Choice

200+ bought in past month

Price: £17.97 (€0.36 / count)

FREE Returns

Voucher: Save 30%:Voucher applies to

Subscribe & Save purchase option only.

Shop items > | Terms



KREON 25000 iu 100 Capsules,2
Packs 100 Each

Brand: Generic
Search this page



Currently unavailable.
We don't know when or if this item will be back in stock.

| | |
|-------------------------|---------|
| Brand | Generic |
| Item form | Capsule |
| Age range (description) | Adult |
| Package information | Bottle |

Product Description



Now Foods Pancreatin 2000

Pancreatin capsules

This high-quality Now Foods product contains **high-dose pancreatin from pigs**.

Pancreatin is a **mixture of digestive enzymes** produced in the pancreas.

- 200mg pancreatin per daily dose
- thereof 50000 USP amylase
- thereof 50000 USP protease
- thereof 4000 USP lipase



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What are we seeing in clinical practice

- *"We are meeting with some family from South Africa, and they are bringing over a month's supply of Creon (at a cost of £450!) as it simply isn't any available here".*
- *"I'm down to my last 2 days worth, but my GP Pharmacist said I'll just have to go without until a supply comes in"*
- *"After ringing around local pharmacies in search of Creon without success, Googling 'Creon supplies' enabled me to find a site selling something similar."*
- *"My symptoms are so bad I can't work at the moment – I can't get half-way up a tree before I need the loo, and there is no public toilets nearby" – tree surgeon*
- *"My GP surgery told me there was nothing they could do, and I should contact the hospital"*
- *"I've got 4 prescriptions in different pharmacies, none of them can get any in, and my surgery won't give me an alternative as I already have already had 4 prescriptions"*



**Not
helpful!**



THE SUNDAY TIMES

‘It’s all-consuming’: cancer patients ration food as drug runs dry

Most of the 10,000 people with pancreatic cancer in England need Creon to help with digestion

Shaun Lintern, Health Editor

21 Jul 2024 00:41:08

The charity Pancreatic Cancer UK has published guidance for patients on how to change their diets and cope with low supplies of Creon. **The British Dietetic Association has issued advice for health teams and said that if patients cannot access enough Creon then “reducing their oral intake of food significantly” may be the best option in the short term.**



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Case Study

- 81-year-old patient lives alone
- Total Pancreatectomy for pre-malignant disease 4 years ago
- Telephoned as hypo'ing more frequently and 2kg weight loss
- Concern as does not detect his hypo's very well – reliant on continuous glucose monitoring device alarms
- Was in the pharmacy at the same time as the father of a child with cystic fibrosis who was really worried about the supply issue, so halved his PERT dose to try and help preserve stocks. He gave half his supply away. Now taking 50% prescribed dose – diarrhoea +++
- “I'd rather the young'un's had them than old men like me”



Joe Bloggs

Breakfast – 3 x Weetabix, full fat milk and a banana with 3 x Creon 25,000

Mid-morning – cup of tea and 2 rich tea biscuits with 1 x Creon 25,000

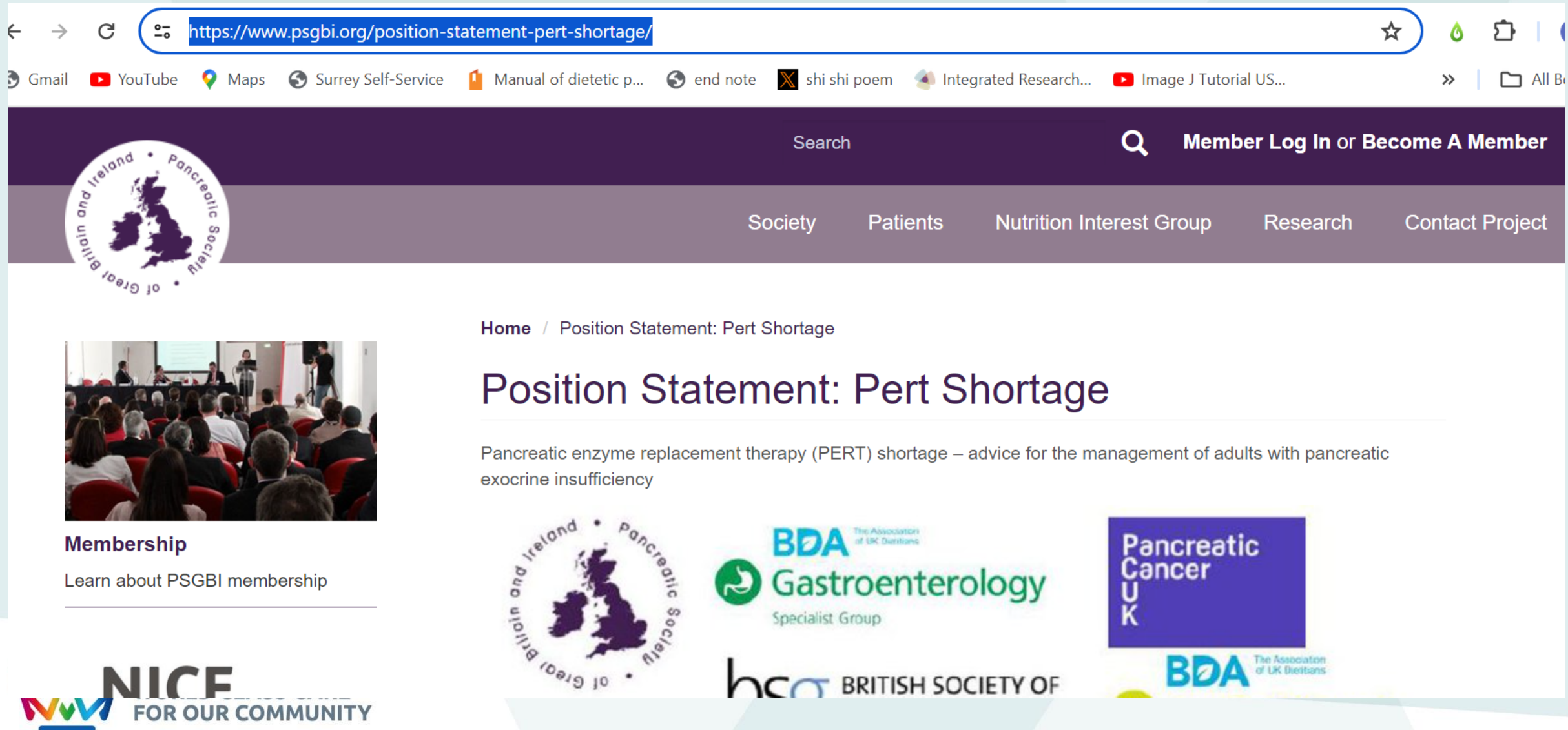
Lunch – Ham sandwich, apple and low-fat yoghurt with 3 x Creon 25,000

Dinner – Spaghetti bolognaise, garlic bread and ice cream with 3 x Creon 25,000

Weight stable, BMI 32, and bowels were well controlled on prescribed dose



Up to date Position Statements



The image is a screenshot of a web browser displaying the PSGBI website. The address bar shows the URL <https://www.psgbi.org/position-statement-pert-shortage/>. The browser's taskbar at the top includes icons for Gmail, YouTube, Maps, Surrey Self-Service, Manual of dietetic p..., end note, shi shi poem, Integrated Research..., and Image J Tutorial US... The website header features the PSGBI logo on the left, a search bar, and a link for "Member Log In or Become A Member". Below the header is a navigation menu with links for "Society", "Patients", "Nutrition Interest Group", "Research", and "Contact Project". The main content area has a breadcrumb trail: "Home / Position Statement: Pert Shortage". The title of the page is "Position Statement: Pert Shortage". The introductory text reads: "Pancreatic enzyme replacement therapy (PERT) shortage – advice for the management of adults with pancreatic exocrine insufficiency". On the left side, there is a thumbnail image of a conference or meeting, with a caption "Membership" and the text "Learn about PSGBI membership". At the bottom of the page, there are logos for NICE (FOR OUR COMMUNITY), the PSGBI logo, BDA Gastroenterology Specialist Group, hscq BRITISH SOCIETY OF, Pancreatic Cancer UK, and BDA The Association of UK Dietitians.

[Home](#) / [Position Statement: Pert Shortage](#)

Position Statement: Pert Shortage

Pancreatic enzyme replacement therapy (PERT) shortage – advice for the management of adults with pancreatic exocrine insufficiency

Membership
Learn about PSGBI membership

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PSGBI
of Great Britain and Ireland • pancreatic Society

BDA The Association of UK Dietitians
Gastroenterology
Specialist Group

hscq BRITISH SOCIETY OF

Pancreatic Cancer UK

BDA The Association of UK Dietitians

What can specialist centres do?

- Support and reassure
- Rescue prescriptions where needed
- Liaise with local medicines management teams to support primary care processes – PERT is not a common medication in primary care – there will be limited experience – so your help is important
- Work with pharmacy team to make DTC applications for imported medications / additional peptide formulae if needed
- Respond promptly to “advice and guidance requests”
- Consider putting this on your Trust risk register
- Out of office with information on supply issues and initial guidance



What do patients need from the Community

- There is a 10% deficit in supply across the UK – **we need to import**
- This is due to continue until 2026, so we need a long-term plan
- Supplies are intermittent, please do not be reassured when you get stock in, this does not mean the problem is over
- Use “back order” system if possible – these will eventually be filled.
- Patients “going without” is not an acceptable option
- Patients are scared



Conclusion

- This is a long-term issue
- Supply does not meet demand; we need to establish imported medicines to regulate supply for patients
- Clinical impact on patients is significant – consider not only abdominal symptoms and malnutrition, but fitness for surgery, tolerance of chemotherapy, absorption of other medications, glycaemic control, risk of falls.....
- Associated costs/impact – multiple prescriptions, patients unable to work, quality of life, some patients may not ever get to curative treatment as a result.
- Patients are petrified and receiving incorrect advice – we need to ensure a consistent message
- Demand on specialist centres is really high – this affects our entire caseload.
- There are a lot of patients out there with no access to tertiary centres – we need a primary care-based solution for them



**Thank you for all your help supporting
our vulnerable patients**



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Any Questions / Comments / Suggestions?



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