The PERT shortage....



Medicine Supply Notification

Pancreatic enzyme replacement therapy (PERT) Tier 2 – medium impact*



"What do you want? I've got Calpol, cough syrup, children's aspirin..."







Shortage of Pancreatic enzyme replacement therapy (PERT)

Mary Phillips, Advanced Clinical Practitioner (HPB Dietetics)



NHS medicines shortage putting lives at risk, pharmacists warn

Unpublished figures reveal a doubling of products in short supply over past two years

- "The worst I've known it': the struggle to get vital medicines
- Analysis: why is UK being hit by medicine supply shortages?





'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.





'I can only eat once a day to make my medication last'



2015

Shortages of Creon 40,000 started

2019

Creon 40.000 discontinued

BREXIT and COVID temporary shortages

Clinical awareness of stock shortages

Viatris issue stock pressure letters

October 2023

Pancrease HL Discontinued 19th Feb 2024

Medicines Supply Notification – change to Creon 10,000

Manufacturer advise will be able to cover additional demand

26th April 2024 Creon 10.000 to

go out of stock

Nutrizym 22 out of stock

9th May 2024

Medicines supply notification (MSN) 22nd May 2024

National patient safety alert (NPSA)

Serious shortage protocol (SSP)



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March 20, 2015 at 3:26 pm | In Prescribing Extra - Drugs | Print | 38 Comments







February 2019

Dear

Re: Important Information About Creon (Pancreatin) 40,000

As you have been prescribed Creon, we would like to inform you that Mylan the marketing authorisation holder for Creon, has decided to voluntarily discontinue the manufacture and distribution of Creon 40,000 from June 2019. It's important to note that this decision is not associated with any safety or efficacy findings.

2015

Shortages of Creon 40,000 started 2019

Creon 40,000 discontinued BREXIT and COVID temporary

shortages

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Viatris issue stock pressure letters

Me

October 2023
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22nd May 2024

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Serious shortage protocol (SSP)





Medicine Supply Notification: Pancrease® HL gastro-resistant capsules

Dispensing & Supply | Shortages



Thursday 12th October 2023

2015

Shortages of Creon 40,000 started

2019

Creon 40.000 discontinued **BREXIT and COVID**

temporary shortages

Clinical awareness of stock shortages

Viatris issue stock pressure letters

October 2023

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Medicines supply notification (MSN)

22nd May 2024 National patient safety alert (NPSA) Serious shortage protocol (SSP)





Supply constraint of Creon® 25000 (Pancreatin) 14th March 2024

As the marketing authorisation holder and distributor of Creon[®] in the UK, we have been notified by our third-party manufacturing partner, Abbott, of an intermittent out of stock period of Creon[®] 25000 (pancreatin) until w/c 8th April 2024.

2015

Shortages of Creon 40,000 started

2019

Creon 40,000 discontinued BREXIT and COVID temporary

shortages

Clinical awareness of stock shortages

Viatris issue stock pressure letters

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Medicine Supply Notification

Pancreatic enzyme replacement therapy (PERT) Tier 2 – medium impact*

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Supply constraint of Creon® 10000 Creon® 25000 (Pancreatin)

26th April 2024

2015

Shortages of Creon 40,000 started 2019

Creon 40,000 discontinued BREXIT and COVID

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Shortage of Pancreatic enzyme replacement therapy (PERT)

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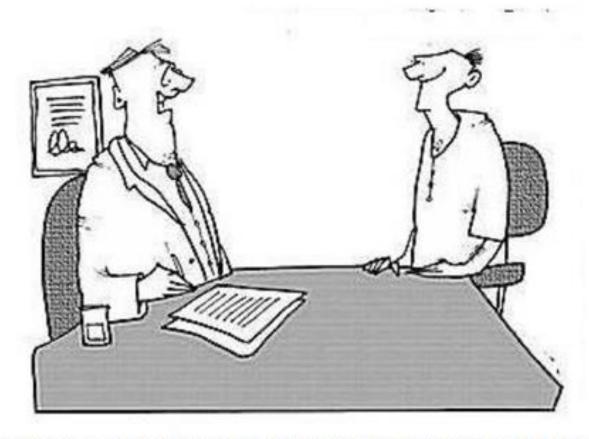
Medicines supply notification (MSN)

22nd May 2024

National patient safety alert (NPSA)

Serious shortage protocol (SSP)





There's a drug shortage. I'm thinking of replacing your meds with eight hugs a day before & after meals!





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.

- Altering product supply to meet patient's needs
- Do not stockpile medicines
- Check expiry dates





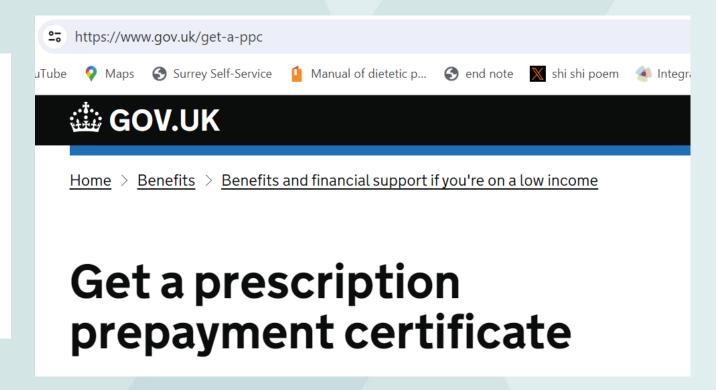
Advice to GP's & Community Pharmacists

Prescribe one month's worth at a time



Medicine Supply Notification

Pancreatic enzyme replacement therapy (PERT) Tier 2 – medium impact*





Phase 2: Limited supplies

- Reassure patients
- Ensure optimal use of existing product: timing, storage
- Prioritise Creon 10,000 for children and those unable to swallow larger capsules
- Prioritise Nutrizym 22 for those unable to tolerate Creon
- Consider PPI if not on one already
- If nutritionally well, consider using loperamide to optimise bowel symptoms rather than a dose escalation
- If gastrically fed, consider giving PERT via PEG/NG at mealtimes in those eating alongside feed.
- Consider peptide ONS in place of polymeric to reduce need for PERT



Phase 2: Advice to GP's and Community Pharmacists

- Prescribe one month's worth at a time
- PERT can only be ordered once the prescription has been issued
- 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 valid at Hospital Pharmacies



Medicine Supply Notification

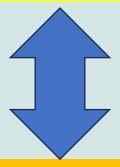
Other considerations

- Vitamin K patients on anti-coagulation should be flagged to their GP as may need more regular monitoring
- Medication absorption seizure medication, oral contraceptive pills.
 Consider a secondary form of contraception at this time.



Current phase

Phase 2



Phase 3



Insufficient supply

- Reduce dose
- For total pancreatectomy / difficult to control diabetes
 - rescue prescription from local hospital



Advice to GP's & Community Pharmacists

- Consider importing medicines from abroad
- Step by step process in the MSN on how to do this.





Pancreatic enzyme replacement therapy (PERT)
Tier 2 – medium impact*



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)



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 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



Nutritional support without PERT

- Peptide formulae is first line
- Fat free ONS if patients are weight stable 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 malabsorbing / nutritionally compromised Emsogen® (Note Elemental 028 Extra® is only 35% MCT)



- Diabetes Control (insulin / OHGA)
- Ensure thorough monitoring for hypoglycaemia
- Advise BG control may be more erratic
- Careful with driving / ensure hypo awareness
- Continuous glucose monitoring will be very useful here set the hypo alert
- Ensure hypo treatment carried at all times



Other considerations

- Vitamin K patients on anti-coagulation should be flagged to their GP as may need more regular monitoring
- CF patients contact local CF centre slightly different advice for this patient group
- Medication absorption seizure medication, oral contraceptive pills. Consider a secondary form of contraception at this time.



If no supplies at all:

- Losing weight
- Uncontrollable bowel symptoms
- Drug absorption consider seizure medications / anticoagulation / OCP
- Move to peptide based ONS (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



Imported medications: considerations



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





Pancreaze (VIVUS)







Preparation	Pack size	Description	Amylase	Protease	Lipase
PANCREAZE Delayed-	100	Light orange body, clear cap VIVUS MT2	15,200	8,800	2,600
release capsules	100	Yellow opaque body, clear cap, VIVUS and MT4	24,600	14,200	4,200
(Made by Vivus)	100	Flesh opaque body and clear cap VIVUS and MT10	61500	35500	10,500
(Imported by Alium)	100	Flesh opaque body and clear cap VIVUS and MT16	98,400	56,800	16,800
,a,	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



https://pancreaze.com/

PANCREAZE strengths (lipase units) OBJECTS ARE SHOWN AT RELATIVE SIZE IT 37 If 37

10,500

https://pancreaze.com/taking-pancreaze/

16,800

21,000

37,000

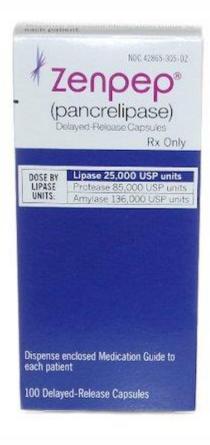


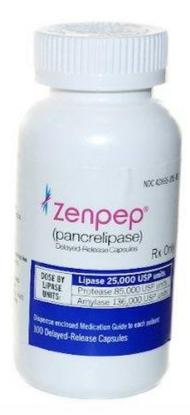
2,600

4,200

0.705"

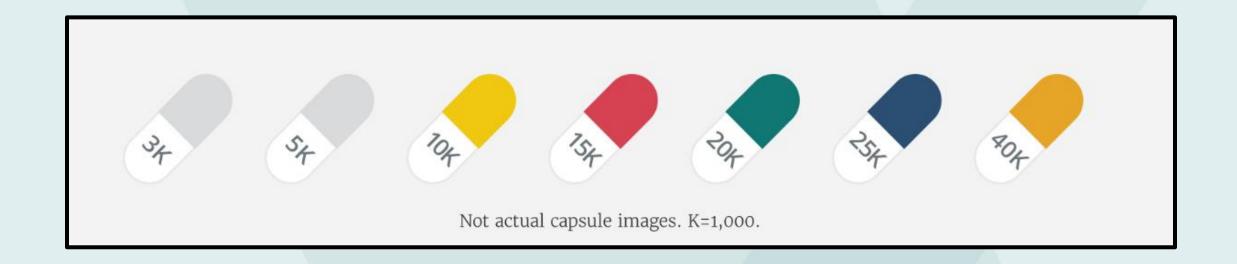
Zenpep (Nestle)







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	100	White body and cap APTALIS 5 (in blue)	24,000	17,000	5,000
capsules (Made by	100	White body and yellow cap APTALIS 10	42,000	32,000	10,000
Nestle)	100	White body and red cap APTALIS 15	63,000	47,000	15,000
(imported by	100	White body and green cap APTALIS 20	84,000	63,000	20,000
Durbin)	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)





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

chrome-

extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.accessdata.fd a.gov/drugsatfda_docs/label/2012/022542s000lbl.pdf





Be careful.....





PCINCIPOTIC DIGESTIVE Enzymes

PCINCIPOTIC DIGESTIVE

PCINCIPOTIC DIGESTIV

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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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

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



UK medications are licenced

- Prescriber takes on all the risk
- Be aware of local formulary restrictions
- Need MHRA approval
- 1-4 weeks lead time

Status	Description
Preferred	Product has been agreed as the preferred choice for initiation and continuation in Primary, Secondary or Tertiary care settings.
GREEN	Product has been agreed as appropriate for initiation and continuation in Primary, Secondary or Tertiary care settings.
Amber *	Now referred to as "Blue" but some Amber Star drugs remain pending review. Prescribing initiated and stablised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement. Please note that in some circumstances a specialist may recommend that prescribing can be started in primary care.
BLUE	Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement. Please note that in some circumstances a specialist may recommend that prescribing can be started in primary care.
AMBER	Prescribing initiated and stabilised by specialist but has potential to transfer to primary care under a formal shared care agreement
RED	Product is for specialist use in secondary / tertiary care. Prescribing to be initiated and continued by the specialist clinician.
BLACK	Not to be routinely commissioned (prescribed) in any care setting (primary or secondary care). This may be due to a lack of good clinical evidence, cost effectiveness, concerns over safety or due to the availability of more suitable alternatives. These are drugs that have been reviewed by the Prescribing Clinical Network and are not recommended for use in any healthcare setting across Surrey & North West facing Sussex health economy. As such, drugs classified as Black should be considered as non-formulary.
	Initiation of this drug is NOT recommended in any health care setting across Surrey & North West facing Sussex CCGs. Prescribers can, however, continue to prescribe for patients already taking this drug
отс	Patients should be advised to purchase if appropriate.



Patient information

https://gutscharity.org.uk/2024/04/pert-supply-problems/

https://www.pancreaticcancer.org.uk/information/managing-symptoms-and-side-effects/diet-and-pancreatic-cancer/pancreatic-enzyme-replacement-therapy-pert/how-to-deal-with-creon-nutrizym-or-pancrex-supply-issues/



What can specialist centres do?

- Support
- Rescue prescriptions where needed?
- Liaise with local medicines management teams
- Work with pharmacy team to make DTC applications for imported medications if needed
- Consider putting this on your Trust risk register
- Out of office with information on them





Case Study

- 81-year-old patient
- 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 worried about the supply issue, so halved his PERT dose to try and help preserve stocks
- "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 well controlled on current dose



Up to date Position Statements

