

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

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Position statement and advice for prescribers from the ¹Nutrition Interest Group of the Pancreatic Society of Great Britain and Ireland (NIGPS), ² Cystic Fibrosis Specialist Group and ³ Gastroenterology Specialist Group, British Dietetic Association.

Endorsed by the British Society of Gastroenterology (Pancreas section); Pancreatic Society of Great Britain and Ireland, Pancreatic Cancer UK, GUTS UK, Cystic Fibrosis Trust, CF Medical Association, Pancreatic Cancer Action, Neuroendocrine Cancer UK and the British Dietetic Association.

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

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Version Control

| Version 2 | Additions | Removal |
|--|--|--|
| Updated | PAGE 4 | PAGE 4 |
| 9/5/24 Due to change in MSN advice | Please refer to the latest The Department of Health and Social Care (DHSC) medicines supply notification regarding supply available within the UK. These are updated regularly. Creon 10,000 should be prioritised for children and those unable to swallow | The Department of Health and Social Care (DHSC) medicines supply notification (issued 16/2/24 MSN/2024/022) has advised that there should be sufficient stock of Creon 10,000 to cover the deficit in Creon 25,000 and Nutrizym 22 (4) |
| | Nutrizym 22 should be prioritised for those unable to tolerate Creon preparations | |
| Updated 9/5/24 | | PAGE 5 Alternative prescriptions to minimise disruption and pill burden to the patient, and |
| Due to changes in MSN advice to avoid additional Creon 10,000 prescribing | | reduce usage of Creon [®] 25,000 could be:Creon [®] 25,000 x 3 with meals and Creon [®] 10,000 x 5 with snacks or Creon [®] 10,000 x 8 with meals and Creon [®] 10,000 x 5 with snacks.or Creon [®] 10,000 x 8 with meals, Pancrex [®] 340mg x 6 with snacks.or Nutrizym [®] 22 x 3 with meals, Pancrex [®] 340mg x 6 with snacksor Pancrex [®] 340mg x 10 with a meal, Pancrex [®] 125mg x 16 with a snack |
| Updated 9/5/24 Due to change in MSN advice | PAGE 6 In line with the Medicines Supply Notification from the Department of Health and Social Care (issued 16/2/24 MSN/2024/022). Please ensure that only one-month supply is issued at a time. (4) | PAGE 6 In line with the Medicines Supply Notification from the Department of Health and Social Care (issued 16/2/24 MSN/2024/022). Please ensure that only one-month supply is issued at a time, and new patients are started on Creon [®] 10,000. (4) |
| Updated 9/5/24 Error in first document. Not ACBS approved | | PAGE 8 ProSource 20 [®] 90kcal, 20g protein (as peptide), 0g fat, 2g carbohydrates. ACBS approved. 60ml serving, take straight from cup or add to hot/cold drinks. |
| Updated 5/5/24 New information | PAGE 10 Link to information available from Pancreatic Cancer UK, Guts UK and the CF Trust | |

| Version 3 | Additions | Removal |
|------------------------|--|--|
| Updated | PAGE 6 | |
| 24/6/24 | Patients who take somatostatin | |
| | analogues [Lanreotide | |
| Additional | (Somatuline [®]) / Octreotide | |
| text added | (Sandostatin [®])] for the treatment | |
| | of neuroendocrine tumours | |
| | (NETs) are also at risk of PEI. | |
| | | |
| | A separate document is available | |
| | providing advice for patients. | |
| | The most up to date version will | |
| | be available at: | |
| | https://www.psgbi.org/position- | |
| | statement-pert-shortage/ | |
| Updated | PAGE 7 | PAGE 7 |
| 24/6/24 | It is likely that imported | "primary care team" changed to "prescriber" |
| | medications may be needed and | |
| Additional information | details on these are provided | |
| in line with | within the appendices. Please liaise with your local pharmacy | |
| NPSA alert | teams regarding access to | |
| INF SA dien | imported medication. | |
| Updated | PAGE 8 | |
| 24/6/24 | Please be aware that patients | |
| Updated - | with small bowel NETs may be at | |
| product | risk of Carcinoid syndrome, | |
| back in | mesenteric fibrosis, short bowel | |
| stock | syndrome etc, please refer to | |
| | their managing Consultant. | |
| | | |
| | Survimed OPD 1.5kcal | |
| Updated | PAGE 9 | PAGE 9 |
| 24/6/24 | Survimed OPD 1.5kcal added to | Powerski - |
| | table 2 | Removed |
| Updated to | Small amounts of fruit and | We suggest patients place their prescription |
| reflect | vegetables can be consumed | requests 2 weeks earlier than usual to give |
| product back in | alongside these drinks. For those | the community pharmacist time to source the medication if available. |
| stock, | who do not have diabetes, sugary drinks and sweets can also be | THE GIVALIOT II AVAIIANE. |
| request for | consumed. These should not | |
| detailed | worsen symptoms but will not | |
| advice and | provide any protein, so should | |
| change in | only be used to improve satiety | |
| prescription | and quality of life. | |
| advice | We suggest patients place their | |
| | prescription requests as soon as | |
| | their previous prescription has | |
| | been dispensed to give the | |
| | community pharmacist time to | |
| | source the medication if available. | |
| | Please ensure that automated | |
| | prescription systems do not reject | |
| | these prescription requests. | |

| Updated 24/6/24 Added reference to NET patients Updated 24/6/24 | Patients have been advised to check these prescription requests are processed. PAGE 10 Only dose escalate PERT in nutritionally compromised patients – liaise with medical teams to access loperamide for those who are weight stable to minimise any diarrhoea (Not appropriate for patients with CF or some patients with NETs Survimed 1.5kcal OPD® added Statement of caution for patients with NETs at risk of Carcinoid Syndrome. PAGE 11 Survimed® OPD 1.5kcal drink – 300kcal, 15g protein (as peptide), 50% MCT, ACBS approved, 200ml bottle, once open store in a refrigerator and discard after 24 | PAGE 10 Survimed 1.5kcal OPD[®] is currently out of stock and has a lower MCT content For patients without CF - If the steps within this guidance are not adequate, please contact your local tertiary pancreatic centre for further advice. |
|--|--|--|
| Undeted | | |
| Updated 24/6/24 New information | Link to Neuroendocrine Cancer UK patient information | |

Introduction

The ongoing supply issues surrounding pancreatic enzyme replacement therapy (**PERT** – under the product brands: **Creon**®, **Nutrizym**® and **Pancrex**®) has progressed. These intermittent supply issues mean some people are running out of PERT, or experiencing difficulties or delays in accessing PERT. Therefore, there is a need for clinical and symptom management advice that is different to normal clinical practice. This position paper is designed to meet the needs of the clinicians' managing patients with pancreatic exocrine insufficiency (PEI) and provides advice for prescribers, and dietitians. A separate document is available providing advice for patients.

Pancreatic enzyme replacement therapy is prescribed to support adequate digestion in patients with PEI, most commonly due to pancreatic cancer, pancreatitis and cystic fibrosis (CF). There are many other clinical situations where patients may have primary or secondary PEI, type 3c diabetes or following gastrectomy or gastric bypass surgery (1). Patients who take somatostatin analogues [Lanreotide (Somatuline®) / Octreotide (Sandostatin®)] for the treatment of neuroendocrine tumours (NETs) are also at risk of PEI. Regardless of aetiology, the impact of maldigestion varies from person to person in both the type of symptoms and their severity.

Symptoms of untreated PEI may include bloating, excess wind, diarrhoea, crampy abdominal pain, faecal urgency, steatorrhoea (pale floating stools), hard to manage blood glucose levels, vitamin and mineral deficiencies, weight loss and malnutrition (1). These symptoms are usually managed with PERT and will recur if patients are unable to take adequate doses.

There are many clinical impacts of inadequate PERT, which will affect all patients, and the advice in this document is targeted at all patient groups. However, particular care should be taken in ensuring absorption is adequate in patients with:

- Cystic fibrosis on CFTR modulators and anti-rejection medication as malabsorption may impact the efficacy of their treatment.
- Patients who have had a total pancreatectomy
- Patients who have had head of pancreas surgery for diseases in the peri-ampullary region (including but not limited to: pancreatic / duodenal / distal cholangio / ampullary cancers, neuroendocrine tumours and pre-malignant conditions)
- Patients with pancreatic cancer undergoing chemotherapy as poor performance status due to malabsorption and malnutrition may prevent patients from undergoing potentially curative or life-prolonging treatments.
- Patients taking somatostatin analogues for NET
- Patients with PEI and insulin dependent diabetes
- Any patient with PEI (including pancreatitis, pancreatic cancer, cystic fibrosis, post gastrectomy etc.,) who are struggling to maintain their nutritional status.

The advice in this paper may be updated as we receive further guidance and expand our experience in managing PEI without adequate PERT. The most up to date version will be available at: https://www.psgbi.org/position-statement-pert-shortage/

Please note the advice in this document is designed for adults with PEI, specialist advice should be sought for children with PEI. Patients with cystic fibrosis will be under the care of a specialist centre, and they should contact their specialist team if they have any concerns.

Advice for Prescribers

Patients with PEI prescribed PERT are likely to need a change in their repeat prescriptions due to the changing availability of products. Unfortunately, this may need to be altered on each prescription depending on product availability.

It may be necessary to provide a range of pancreatic enzymes to meet the needs of patients and repeat prescriptions should be flexible to allow for this. Pharmacists are unable to dispense anything other than the medication prescribed, so patients do have to return to their prescriber to obtain a new prescription when they are unable to access the product prescribed.

Please refer to the latest The Department of Health and Social Care (DHSC) medicines supply notification regarding supply available within the UK. These are updated regularly.

- Creon 10,000 is only being delivered to hospitals and should be prioritised for children and those unable to swallow larger capsules
- Nutrizym 22 is not available until after August 2024 and should be prioritised for those unable to tolerate Creon preparations

It is likely that imported medications may be needed and details on these are provided within the appendices. Please liaise with your local pharmacy teams regarding access to imported medication. There is no evidence to suggest that there is any difference between European and American units of enzymes in these preparations (6)

| Creon [®] 25,000 Dose | Equivalent in Nutrizym [®] 22 | Equivalent in Creon [®] 10,000 | Equivalent in Pancrex [®] 340mg (8,000 units lipase) | Equivalent in Pancrex [®] 125mg (2,950 units lipase) | Equivalent in Creon [®] Micro* | Pancrex [®] V powder* |
|--------------------------------------|---|---|--|--|---|-----------------------------------|
| 1 x Creon | 1 x | 3 x Creon | 3 x Pancrex | 8 x Pancrex | 5 scoops | ½ x 2.5ml |
| 25,000 | Nutrizym 22 | 10,000 | 8,000 | 2,950 | Creon Micro | spoon |
| 2 x Creon | 2 x | 5 x Creon | 6 x Pancrex | 16 x Pancrex | 10 scoops | 1 x 2.5ml |
| 25,000 | Nutrizym 22 | 10,000 | 8,000 | 2,950 | Creon Micro | spoon |
| 3 x Creon | 3 x | 8 x Creon | 9 x Pancrex | 24 x Pancrex | 15 scoops | 1½ x 2.5ml |
| 25,000 | Nutrizym 22 | 10,000 | 8,000 | 2,950 | Creon Micro | spoon |
| 4 x Creon | 4 x | 10 x Creon | 12 x Pancrex | 32 x Pancrex | 20 scoops | 2 x 2.5ml |
| 25,000 | Nutrizym 22 | 10,000 | 8,000 | 2,950 | Creon Micro | spoon |
| 5 x Creon | 5 x | 13 x Creon | 15 x Pancrex | 40 x Pancrex | 25 scoops | 2 ½ x 2.5ml |
| 25,000 | Nutrizym 22 | 10,000 | 8,000 | 2,950 | Creon Micro | spoon |
| 6 x Creon | 6 x | 15 x Creon | 18 x Pancrex | 48 x Pancrex | 30 scoops | 3 x 2.5ml |
| 25,000 | Nutrizym 22 | 10,000 | 8,000 | 2,950 | Creon Micro | spoon |

Table 1: Conversion charts (2)

*Mix with a mildly acidic puree (fruit yoghurt / apple sauce), rinse mouth with water and ensure thorough mouth care as at risk of ulceration if powder / granules get stuck in the gums / under dentures

Taking the PERT throughout the meal rather than all at the start/ middle/ end improves efficacy.

Other clinical management suggestions:

- Consider prescribing a **proton pump inhibitor** or **H2 receptor antagonist** to reduce acid degradation of the PERT and optimise efficacy in patients where there are not any contra-indication (1).
- In patients who are experiencing loose bowel motions or faecal urgency due to lack of PERT, and WHO DO NOT HAVE CYSTIC FIBROSIS and where an infective, inflammatory (underlying inflammatory bowel disease) or obstructive cause has been ruled out - please consider prescribing loperamide at a starting dose of 2mg in the morning and working up to 2mg before meals (TDS) if needed. Higher doses may be needed and should be assessed individually. This will slow the gut transit time down and help alleviate symptoms but will not treat malabsorption.
- Distal intestinal obstruction syndrome is a unique feature of CF and is characterised by the accumulation of viscid mucofaecal material in the terminal ileum and caecum. Being a common complication in people with CF, it needs to be considered if someone with CF presents with symptoms following a change in their PERT prescription.
- Be aware that patients on insulin or oral hypoglycaemic agents that can cause hypoglycaemia may experience worsening control and be more susceptible to hypoglycaemia. Regular blood glucose monitoring is helpful, and patients on continuous glucose monitoring should be encouraged to ensure their hypoglycaemic alarm is set.
- If your patient has a gastric feeding tube [Percutaneous Endoscopic Gastrostomy (PEG), Radiologically inserted gastrostomy (RIG) or naso-gastric (NG) tube] then they can receive their PERT through the feeding tube in the form on **Pancrex® V powder**. This should be made up each time, the powder mixed with 20mls of water and flushed down the tube. 2g is 50,000 lipase units, this fills the 2.5ml end of a measuring spoon. This should be flushed through the tube during the meal (1) (Appendix 2). Please note, this dose may need to be escalated.
- In patients who have ongoing bowel symptoms and were undergoing dose escalation to manage this, please only continue to increase the dose until the patient is able to maintain their weight. If they have ongoing bowel symptoms after this, we suggest using **loperamide** / **Buscopan**[®] and other appropriate medications to manage their symptoms rather than continuing to increase the doses to preserve supplies. **Imodium melts**[®] may be more effective than loperamide capsules. (Please do not do this for patients with Cystic Fibrosis advice should be sought from their specialist team).
- Please be aware that patients with small bowel NETs may be at risk of Carcinoid syndrome, mesenteric fibrosis, short bowel syndrome etc, please refer to their specialist teams if you have concerns.
- Consider that patients with PEI, may also have bile acid malabsorption, small intestinal bacterial overgrowth, coeliac disease etc., please investigate and treat in line with current guidelines (2).
- If patients are unable to access any PERT and are losing weight or have intractable or unmanageable abdominal symptoms, we suggest reducing their oral intake of food significantly and prescribing peptide based oral nutritional supplements instead (Vital 1.5kcal[®] or Survimed OPD 1.5kcal[®], Peptisip Energy HP[®]). Please note this should be used for a short period until further supplies of PERT can be obtained. We recommend you only prescribe one-week supply at a time, due to the cost of these products. Please note standard oral nutritional supplements are NOT suitable without PERT (i.e., Altraplen[®] Aymes[®], Ensure[®], Foodlink[®] Fortisip[®], Fresubin[®]). Table 2 shows prescription doses by body weight.
- Consider prescribing a calcium and vitamin D supplement if patients are not already taking one (please seek advice from specialist teams for patients with cystic fibrosis).
- Please be aware that malabsorptive diarrhoea may impact the absorption of other medication (including medication prescribed for seizures, the oral contraceptive pill etc.,)
- Please be aware that Vitamin K is a fat-soluble vitamin and uptake maybe impaired with inadequate PERT additional monitoring may be needed for patients on anti-coagulation.

Table 2: How many nutritional supplement drinks should be prescribed for patients not able to absorb food and without access to PERT.

| Body weight | Supplements needed per day (Vital 1.5kcal [®] or Survimed OPD 1.5kcal or Peptisip Energy HP [®] |
|-------------|---|
| Below 40kg | Contact a dietitian |
| 40 - 50kg | 4 x 200ml bottles = 1200kcal |
| 50 - 60kg | 5 x 200ml bottles = 1500kcal |
| 60 - 70kg | 6 x 200ml bottles = 1800kcal |
| 70 - 80kg | 7 x 200ml bottles = 2100kcal |
| 80 - 90kg | 8 x 200ml bottles = 2400kcal |
| Over 90kg | Contact a dietitian |

This may under-estimate energy needs, however it should be sufficient for short term nutritional support. If needed for longer and the patient is rapidly losing weight or is very active, add in one more bottle per day. If they gain weight and were not intending to – reduce by 1 bottle per day.

Small amounts of fruit and vegetables can be consumed alongside these drinks.

For those who do not have diabetes, sugary drinks and sweets can also be consumed.

These should not worsen symptoms but will not provide any protein, so should only be used to improve satiety and quality of life.

IMPORTANT

Whilst the supply issues are ongoing, please do **NOT** encourage patients to stockpile these medicines, as this will further drive the shortage.

We suggest patients place their prescription requests as soon as their previous prescription has been dispensed to give the community pharmacist time to source the medication if available. Please ensure that automated prescription systems do not reject these prescription requests. Patients have been advised to check these prescription requests are processed. Please provide PERT prescriptions on singular prescriptions to allow patients to take prescriptions to a different pharmacy to those who dispense their other medicines.

If you are issuing multiple prescriptions so patients can try and source different products, please advise them to try to use one pharmacy if leaving prescriptions on a "back order" to try to reduce the risk of large volumes being dispensed by different pharmacies.

In line with the Medicines Supply Notification from the Department of Health and Social Care (issued 16/2/24 MSN/2024/022). Please ensure that only one-month supply is issued at a time. (4). If you are hospital based, please liaise with your pharmacy team regarding stock levels and consider issuing "rescue prescriptions" from the hospital **only in the event that high priority patients have run out completely**. We recommend no more than 1-2 weeks supply is issued within a rescue prescription. Larger prescriptions risk depleting hospital supplies.

Sources of further advice

For patients with CF please contact the patients' CF Specialist team. For all other patients please contact your local tertiary hepato-pancreatico-biliary (HPB) / pancreatic / neuroendocrine unit. Depending on the local service available, this may be either the specialist HPB/ pancreatic / NET dietitian or pancreatologist. The Specialist Pharmacy Service Medicines Supply Tool can be accessed by Prescribers for more information on supply at: <u>https://www.sps.nhs.uk</u>

Advice for Dietitians

In addition to the above advice, please consider the following:

- Remind patients to spread the dose of their PERT out throughout their meals to optimise absorption taking some PERT at the beginning, some in the middle and some towards the end of their meal.
- Remind patients to store their enzymes properly all products should be stored below 25 degrees and some require refrigeration. Excess heat causes irreversible denaturation.
- Only dose escalate PERT in nutritionally compromised patients liaise with medical teams to
 access loperamide for those who are weight stable to minimise any diarrhoea (Not appropriate
 for patients with CF or some patients with NETs). Ensure obstructive / infectious causes have
 been ruled out first. Refer patients not responding to treatment back to their managing
 physician to ensure other causes of diarrhoea have been excluded.
- Use peptide based oral nutritional supplements (ONS). i.e., VITAL 1.5 kcal[®] / Survimed OPD 1.5kcal[®] / Peptisip Energy HP[®] in place of polymeric supplements to reduce the need for PERT with polymeric ONS. Peptamen[®] Vanilla contains less energy (1kcal/ml), but these could be used if supplies of VITAL 1.5 kcal[®] / Survimed OPD 1.5kcal[®] / Peptisip Energy HP[®] are limited.
- Consider fat free ONS sipped slowly without PERT if the patient is weight stable. If the patient experiences significant abdominal symptoms or weight loss despite this, please swap to peptide based ONS. PERT may still be required for polysaccharide and protein digestion. Fat free ONS are not nutritionally complete and should not be used a sole source of nutrition.
- Use **ProSource Jelly**® / **ProSource Plus**® for additional protein (peptide based).
- Medium chain triglyceride (MCT) lipid products (Liquigen[®] / MCT oil[®]) could be used alongside fat free ONS in patients who need higher energy ONS. Please note that Elemental 028[®] contains 35% MCT and still requires PERT for lipid absorption, but Emsogen[®] can also be considered. This can be concentrated if tolerated.
- Consider 10-20% reduction in dietary fat for patients who are symptomatic.
- Consider reducing dietary fibre if large doses are consumed (>40g fibre per day) as high fibre diets can reduce the efficacy of PERT.
- Ensure patients with diabetes on **insulin** or medications associated with hypoglycaemia (i.e. **Gliclazide**) are regularly monitoring their blood glucose levels and aware of how to treat a hypo.
- Please ensure patients with signs of malabsorption and taking anti-coagulation are highlighted to their managing physician as Vitamin K absorption may be impaired.
- Seek advice from specialist centres for specific advice for patients with CF.
 - CF Dietitians will review and optimise PERT dosing and adherence.
 - CF Dietitians will optimise vitamins and minerals and adjust as appropriate.
- Patients with intractable malabsorption may need peptide enteral or in severe cases parenteral nutrition.
- If you work in a tertiary pancreatic / NET centre, please liaise with your pharmacy team
 regarding stock levels and consider issuing "rescue prescriptions" from the hospital in the event
 that high priority patients have run out completely. We recommend no more than 1-2 weeks
 supply issued within a rescue prescription if possible. Larger prescriptions risk depleting
 hospital supplies.

Nutritional composition of additional products

Liquigen[®] 30mls = 136kcal, 0g protein, 97.4% MCT. ACBS approved. 250ml bottle, once open store in a refrigerator and use within 14 days. Suitable for vegans and vegetarians.

Nutricia MCT oil[®] 100mls = 855kcal, 0g protein, 99.9% MCT. ACBS approved. 500ml bottle, once open, reseal and use within 1 month. Suitable for vegans and vegetarians.

Vital 1.5kcal[®] 300kcal, 13.5g protein (as peptide), 64% MCT. ACBS approved. 200ml bottle, suitable for vegetarians (not vegan), once open store in a refrigerator and discard after 24 hours

Peptisip Energy HP[®] 300kcal, 15g protein (as peptide), 60% MCT, ACBS approved, 200ml bottle, suitable for vegetarians (not vegan), once open store in a refrigerator and discard after 24 hours.

Emsogen[®] 438 kcal, 12.5g protein per 100g,(as amino acid), 83% MCT, 88kcal per 100mls, 2.5g protein, ACBS approved. Note this is a low energy, low protein supplement drink. Standard concentration is 20% w/v (1 x 100g sachet in 500mls water). This can be concentrated further if tolerated, but patients may require additional fluids afterwards. Milkshake / coffee syrups can be added to flavour.

ProSource Jelly[®] 90kcal, 20g protein (as peptide), 0g fat, <1g carbohydrates, ACBS approved. 118g serving, serve chilled.

ProSource Plus[®] 100kcal, 15g protein (as peptide), 0g fat, 11g carbohydrates. ACBS approved. 30ml serving, flavoured products can be taken as a shot, unflavoured can be added to drinks or food.

Peptamen Vanilla[®] 200kcal, 8g protein (as peptide), 68% MCT, ACBS approved. 200ml bottle, best served chilled, once open refrigerate and consume within 24 hours.

Survimed[®] **OPD 1.5kcal** drink – 300kcal, 15g protein (as peptide), 50% MCT, ACBS approved, 200ml bottle, once open store in a refrigerator and discard after 24 hours.

Sources of product information

Liquigen (nutricia.co.uk) <u>MCT Oil (nutricia.co.uk)</u> <u>Vital 1.5kcal | Patient Samples Abbott Nutrition UK</u> <u>Peptisip Energy HP (nutricia.co.uk)</u> <u>Emsogen (nutricia.co.uk)</u> <u>Nutrinovo - ProSource Jelly nutrition supplement - Nutrinovo</u> <u>Product: ProSource 20 - Nutrinovo</u> <u>Nutrinovo - ProSource Plus nutrition supplement - Nutrinovo</u> <u>Peptamen Vanilla Liquid Sip Feed | Nestlé Health Science (nestlehealthscience.co.uk)</u> <u>Survimed OPD 1.5kcal Drink Cappuccino | Disease Specific (fresubin.com)</u>

References / sources of further information

- Phillips ME, Hopper AD, Leeds JS, *et al* Consensus for the management of pancreatic exocrine insufficiency: UK practical guidelines *BMJ Open Gastroenterology* 2021 ;8:e000643. doi: 10.1136/bmjgast-2021-000643
- 2) https://bnf.nice.org.uk/drugs/pancreatin/ accessed 16/3/24
- 3) https://cks.nice.org.uk/topics/diarrhoea-adults-assessment/ accessed 16/3/24
- 4) Medicine Supply Notification: Creon 25000 MSN/2024/022 Issued 16/02/24
- 5) <u>A5 Hypo TREND.pdf (trenddiabetes.online)</u> accessed 16/3/24
- 6) https://lp.thieme.de/emag/CP/11525-Drug-Report-Pankreatin-2024/#6
- 7) NPSA

https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103253 accessed 11/6/24

Appendix 1: Table 3: High fat foods and their lower fat alternatives

| | Reduce your portion sizes of these | Have these instead |
|-----------------------------|--|---|
| Fats and oils | Butter, lard, Ghee, Margarine, cooking oils | Small portions of low-fat spreads |
| | | Use spray on cooking oils if needed |
| | Full fat milk / yoghurt | Semi-skimmed or skimmed milk. |
| | Cream | Low fat yoghurts |
| | Crème Fraiche | Use small amounts of grated cheese instead of slices of cheese – choose |
| Dairy products | Cheese | stronger cheeses to maximise taste. |
| | | To increase your protein intake make skimmed milk powder up using skimmed milk and use in place of milk throughout the day |
| | Fried foods or foods | Meat and fish cooked without added oil |
| | cooked in batter | Tinned fish, tinned in spring water / brine |
| Meat and Fish | Skins / visible fat on meat | Timed han, timed in spring water / brine |
| | Tinned fish, tinned in oil | |
| Dianthaaad | Nut butters | Pulses (e.g. lentils, chickpeas, beans (note portion sizes in table 4) |
| Plant based protein sources | | Quorn [®] / Tofu – up to 100g |
| Fruit & vegetables | No restrictions for low | fat, see Table 4 for fibre suggestions |
| | Croissants, pastries | Bread, Breakfast cereals |
| Carbohydrate based foods | Chips / Fried | Potatoes, rice, pasta, cooked without added fat |
| | Roast potatoes | |
| | Cheese based sauces | Tomato based sauces, gravy, mustard, tomato ketchup, soy sauce, mint jelly, |
| Sauces / Condiments | Creamy sauces (bearnaise, hollandaise etc.,) | vinegar or low-fat salad dressings |
| | Large portions of mayonnaise | |

Appendix 2: Table 4: Fibre content of high fibre foods. Aim for less than 40g fibre per day

| Very high | fibre foods | High fibre foods | | | |
|--|------------------------------------|---|----------------------------------|--------------------------------------|----------------------------------|
| Food | Portion providing 10g fibre | Food | Portion providing 5g fibre | Food | Portion providing 5g fibre |
| All bran [®] | 40g | Whole wheat pitta | 1 large | Weetabix® | 2 biscuits |
| Brown pasta | 250g (cooked) | Rye based crackers (i.e. Ryvita [®]) | 4 biscuits | Shredded wheat [®] | 2 biscuits |
| Baked Beans | 300g | Branflakes [®] / Sultana Bran [®] , Fruit n/Fibre [®] | 30g bowl | Porridge / Readybrek [®] | Large bowl (60g oats) |
| Dried apricots / prunes | 120g | Jacket potato with skin | 1 medium | Pasta (white) | 250g (cooked) |
| Nuts and seeds | 150g | Wholemeal spaghetti | 150g (cooked) | Wholemeal bread | 100g |
| Dried lentils / chick peas /Mung beans | 100g (weight before cooking) | Baked beans | 150g | Quorn [®] | 75g |
| Dried soya beans / red kidney beans | 70g (weight before cooking) | Green beans / peas (fresh or frozen) | 120g | Spinach | 5 tablespoons |
| Desiccated coconut | 70g | Sweetcorn | 7 tablespoons | Avocado pear | 1 whole fruit |

Appendix 3: Guide to making up powdered enzymes

Appendix 2: Guide to making up powdered enzymes (Pancrex[®] V powder) for administration through a gastric feeding tube (NG,PEG or RIG) for patients who are eating.



Step 1) You will need a medicine spoon, cooled, boiled water and a pot for mixing in.

Step 2) Wash your hands. If you have eczema or sensitive skin you may wish to wear gloves for this, as Pancrex[®] V powder can be irritant to sensitive skin.



Step 3) The 2.5ml end of a measuring spoon measures 2g of Pancrex[®] V powder (50,000 units of lipase) - measure your dose of powder and place in a small bowl or cup for mixing.

Step 4) Start eating your meal.



Step 5) Once you are halfway through your meal - add 20mls cooled boiled water to the powder and mix with the medicine spoon until the powder is dissolved, don't worry if some seems to stick to the edges.



Step 6) Draw the mixture up into an enteral syringe, if some powder is stuck to the edges, squirt the mixture back into the bowl to knock it off and draw it up again.

Step 7) Flush through your feeding tube and then flush with water as normal.

You will need to do this each time you eat, the powder will only mix with the food in your stomach. If you spend more than 30 minutes eating your meal, you should take another dose.

Appendix 4: Content of imported Pancreatin products

PANCREAZE®

Delayed-release capsules. In order to reduce confusion for patients, we suggest using the 10,500 and 21,000 products which could be used interchangeably with Creon[®] 10,000, Nutrizym $22^{\text{®}}$ or Creon[®] 25,000

| Preparation | Pack size | Description | Amylase | Protease | Lipase |
|------------------------------------|--------------|---|---------|----------|--------|
| PANCREAZE [®] (Made by | 100 | Light orange body, clear cap VIVUS MT2 | 15,200 | 8,800 | 2,600 |
| Vivus) (Imported by Alium) | 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®

Delayed-release capsules. In order to reduce confusion for patients, we suggest using the 10,000 and 25,000 products which could be used interchangeably with Creon[®] 10,000, Nutrizym $22^{\text{®}}$ or Creon[®] 25,000

| Preparation | Pack size | Description | Amylase | Protease | Lipase |
|------------------------------------|--------------|---|---------|----------|--------|
| Zenpep [®] (Made by | 100 | White body and cap APTALIS 3 (in red) | 14,000 | 10,000 | 3,000 |
| Nestle) (Imported by Durbin) | 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 |
| | 100 | White body and red cap APTALIS 15 | 63,000 | 47,000 | 15,000 |
| | 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®

Tablet presentation. Please note these contain Lactose.

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