Recommended Creon® (pancreatin) Dosing

KEY Successful Unsuccessful

Suggested follow-up timing

Week 0

Starting dose of Creon minimicrospheres[1–4]

Main meal (300-600kcal): 2 x Creon 25000

Snacks: 1 x Creon 25000

Explain why patients need to take Creon with meals

Week 1

Recheck dietary intake and ensure adequate acid suppression by use of PPIs

Week 2

Instruct patients to increase dose and consider timing
Titrated dose example

Main meal: 4 x Creon 25000

Snacks: 2 x Creon 25000

Week 3

Check compliance. If patient is still symptomatic or requires more than 100,000 lipase units/meal, consider titrating up to a higher strength (Creon 40,000) to reduce pill burden

Week 4

Instruct patients to increase dose and consider timing
Titrated dose example

Main meal: 3 x Creon 40000

Snacks: 1 or 2 x Creon 40000

Week 5

- Reconsider the diagnosis of pancreatic insufficiency
- Ensure effective acid suppression
- Check coeliac status
- Is biliary obstruction contributing?

Week 6

Increase dose again
If unsuccessful, consider alternative formulation

Treatment is successful

Capsules shown not actual size.

Adapted from Layer P *et al. Curr Gastro Rep.* 2001; Imrie CW *et al. Aliment Pharmacol Ther.* 2010; Lohr J-M *et al. United European Gastroenterol J.* 2013.

Prescribing information can be found overleaf. CRE-2017-0111. Date of preparation: June 2017.

Creon®

Creon Micro Pancreatin 60.12 mg Gastro-resistant Granules, Creon 10000 Capsules, Creon 25000 Capsules, Creon 40000 Capsules: PRESCRIBING INFORMATION

Presentation: *Creon Micro:* Gastro-resistant granules of pancreatin, containing in 100mg: 5,000 PhEur units of lipase; 3,600 PhEur units of amylase; 200 PhEur units of protease. *Creon 10000:* Each capsule contains pancreatin equivalent to: 10,000 PhEur units of lipase; 8,000 PhEur units of amylase; 600 PhEur units of protease. *Creon 25000:* Each capsule contains pancreatin equivalent to: 25,000 PhEur units of lipase; 18,000 PhEur units of amylase; 1,000 PhEur units of protease. *Creon 40000:* Each capsule contains pancreatin equivalent to: 40,000 PhEur units of lipase; 25,000 PhEur units of amylase; 1,600 PhEur units of protease. **Indication:** Pancreatic exocrine insufficiency. **Dosage and Administration:** *Creon Micro:* Initially 100mg (5000 lipase units) taken with each feed or meal or immediately after. The required quantity of granules should be dispensed using the measuring scoop provided which holds 100mg. In young infants, mix with a small amount of (undiluted) apple juice and give from a spoon directly before the feed. In weaned infants, mix with acidic liquids or soft foods (e.g. undiluted apple juice or apple puree) and take directly before the meal without chewing. Alternatively, mix the granules with a small amount of milk on a spoon and administer to the infant immediately. The granules should not be added to the baby's bottle. *Creon 10000, 25000 and 40000*: Initially one or two capsules during or immediately after meals, then adjust according to response. The capsules can be swallowed whole, or for ease of administration they may be opened and the granules taken with acidic fluid or soft food, but without chewing. This could be apple sauce or yoghurt or any fruit juice with a pH less than 5.5, e.g. apple, orange or pineapple juice. *Creon Micro, 10000, 25000 and 40000:* Dose increases, if required, should be added slowly with careful monitoring of response and symptomatology. Maximum daily dosage of Creon Micro should not exceed 10,000 units lipase/kg/day. Ensure adequate hydration. If the granules are mixed with fluid or food, it is important that they are taken immediately and the mixture not stored, otherwise dissolution of the enteric coating may result. In order to protect the enteric coating, it is important that the granules are not crushed or chewed. Crushing and chewing of the minimicrospheres or mixing with food or fluid with a pH greater than 5.5 can disrupt the protective enteric coating. This can result in early release of enzymes in the oral cavity and may lead to reduced efficacy and irritation of the mucous membranes. Care should be taken to ensure that no product is retained in the mouth. Colonic damage has been reported in patients with cystic fibrosis taking in excess of 10,000 units of lipase/kg/day (see below). **Contraindications, Warnings etc:** Hypersensitivity to pancreatin of porcine origin or any excipients. Fibrosing colonopathy has been reported in CF patients taking high dose pancreatin preparations. As a precaution, medically assess unusual or changes in abdominal symptoms, especially for doses above 10000 units of lipase/kg/day. **Pregnancy and Lactation:** There is inadequate evidence of safety in use during pregnancy. Pancreatic enzymes can be used during breast-feeding. **Ability to Drive and Operate Machinery:** No or negligible influence on ability. **Side Effects:** Most commonly, gastrointestinal disorders. *Common:* nausea, vomiting, constipation, diarrhoea and abdominal distension. Gastrointestinal disorders are mainly associated with the underlying disease. Similar or lower incidences compared to placebo were reported for abdominal pain (very common, ≥1/10). *Uncommon:* rash. *Frequency unknown:* Hypersensitivity (anaphylaxis), pruritus and urticaria, strictures of the ileo-caecum and large bowel (fibrosing colonopathy). See SPC for further information. *Interactions*: no studies performed. **Name and Address of Marketing Authorisation Holder:** Mylan Products Ltd., 20 Station Close, Potters Bar, Herts, EN6 1TL **PL No:** Creon Micro: PL 46302/0031, Creon 10000: PL 46302/0028, Creon 25000: PL 46302/0029, Creon 40000: PL 46302/0030 **Basic NHS price:** Creon Micro (20g): £31.50, Creon 10000 (100 capsules): £12.93, Creon 25000 (100 capsules): £28.25, Creon 40000 (100 capsules): £47.55 **Legal Category:** Creon Micro and Creon 10000: P, Creon 25000 and Creon 40000: POM **Further information is available in the UK from:** BGP Products Ltd., Building Q1, Quantum House, 60 Norden Road, Maidenhead, SL6 4AY
Date of Last Revision: 29/03/2017
Veeva reference: CRE-2016-0186

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Mylan by phone 0800 121 8267 or e-mail ukpharmacovigilance@mylan.com.

REFERENCES

1. Creon Micro Summary of Product Characteristics. November 2016.
2. Creon 10000 Capsules Summary of Product Characteristics. January 2017.
3. Creon 25000 Capsules Summary of Product Characteristics. January 2017.
4. Creon 40000 Capsules Summary of Product Characteristics. February 2017.
5. Layer P *et al. Curr Gastroenterol Rep.* 2001; **3:** 101–108.
6. Imrie CW *et al. Aliment Pharmacol Ther.* 2010; **32**(Suppl 1): 1–25.
7. Lohr J-M *et al. United European Gastroenterol J.* 2013; **1**(2): 79–83.

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