

February 2019

Dear

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

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 40K from June 2019. It's important to note that this decision is not associated with any safety or efficacy findings.

Compared to all other doses, producing Creon 40K requires a different concentration of active enzymes which have been decreasing over the last few years and because of this Creon 40K has experienced frequent supply constraints.

It is important to note that, Creon Micro, Creon 10K and Creon 25K will still be available in the UK with increased volumes to compensate for the discontinuation of Creon 40K.

Please note Creon capsules are interchangeable and patients can achieve the higher dose by taking more of the lower strength capsules. Patients should not be concerned about the efficacy when switching to a lower strength capsule.

We will proactively inform patient organisations and healthcare professionals and will also produce supporting materials to increase the awareness of the forthcoming unavailability of Creon 40K.

You may wish to refer to the suggested dosing table below when reviewing your current patients taking Creon 40K¹⁻⁶:

		Starting dose	Increase dose if required (E.g.)	Titrated dose	Increase dose again if required (E.g.)	Titrated dose
		2x Creon 25,000		4 x Creon 25,000		5 x Creon 25,000
Patients with PEI	Meal	2x Creon 25,000		4 x Creon 25,000		5 x Creon 25,000
	Snack	1 x Creon 25,000		2 x Creon 25,000		3 x Creon 25,000

If you have any questions, please contact 01707 853 104.

Medical information requests maybe directed to the Mylan Medical Information department via email; info.uk@mylan.co.uk or via phone; 01707 853 000 (option1)

Yours Sincerely,

Katie Swards

Creon UK Brand Manager

About Creon:

Creon is a Pancreatic Enzyme Replacement Therapy (PERT) that helps patients with Pancreatic Exocrine Insufficiency (PEI) to break down food and digest nutrients by replacing the pancreatic enzymes made by a healthy pancreas. The active substance of Creon is pancreatin, a natural substance from the pancreas of the pig; as a biologic product Creon is produced using a complex manufacturing process that is subject to high standards and strict requirements in terms of quality and compliance.

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, 2017 2.Creon 10000 Capsules Summary of Product Characteristics, 2017 3.Creon 25000 Capsules Summary of Product Characteristics, 2017 4. Layer P et al. Curr Gastroenterol Rep. 2001; 3: 101-108 5. Imrie CW et al. United European Gastroenterol J. 2010;1(2): 79-83 6. Lohr JM et al. United European Gastroenterol J. 2017; 5(2): 153-199

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