

Our ref: JS/NP/L160428a

28 April 2016

Lynne O'Grady
Head of Clinical Programmes
Cystic Fibrosis Trust
One Aldgate,
Second Floor
London
EC3N 1RE

Dear Ms O'Grady

Thank you for your enquiry on the availability of our product Creon® (Pancreatin).

Mylan takes the concerns of the Cystic Fibrosis community very seriously and welcomes the opportunity to assist you in addressing any concerns you may have in regards to our products.

Re: Availability of Creon 40000

Unfortunately Creon 40000 remains unavailable and at this stage we are unable to predict when we may be able to resume normal supply of Creon 40000 in the UK. Creon 40000 has not been withdrawn from the market and there are no plans to withdraw Creon 40000.

As you might be aware Creon is manufactured by Abbott. Mylan only has the distribution rights for this product in the UK and some other countries. However please be assured that Mylan and Abbott are working diligently to re-establish supply.

The reason for the unavailability of Creon 40000 is due to the biologic nature of the product and lower-than-expected concentration of active enzymes available for the production of Creon 40000. 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. Mylan and Abbott, the manufacturer of Creon are working co-operatively and diligently to address this situation as quickly as possible, including identifying additional sourcing options that meet our high quality requirements.

Mylan is also proactively communicating this information to healthcare professionals. Dietitians and physicians involved in the treatment of pancreatic exocrine insufficiency have been fully informed about the supply constraints of 40000. We therefore recommend that patients speak to their healthcare professionals who are best placed to offer advice on their pancreatic enzyme treatment.

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Lynn O'Grady
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Is there an availability of issue with any other Creon strength?

Mylan has experienced a delayed delivery for Creon 25000 in March 2016 which has resulted in reduced stock available.

We can confirm that stock has since then been received and was made available to wholesaler's week commencing 21st March. We are working very closely with our distributor and wholesalers to ensure adequate distribution into pharmacy in order to meet the patient's needs.

We deeply regret the difficulties caused to patients by this situation. Please be assured that Mylan and Abbott will continue to focus every effort to ensure adequate enzyme supply of Creon. Therefore in this particular situation we ask you for your support and understanding.

Yours sincerely



Jamie Sparrow

Vice President, Managing Director
UK & Ireland