



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)

What is Creon used for?	Creon (also marketed as Kreon in certain Member States) contains pancreas enzymes (lipase / amylase / protease) and is used to treat pancreatic exocrine insufficiency (a condition in which the pancreas insufficiently delivers digestive enzymes into the small intestine, thereby preventing food from being fully digested) resulting from other conditions or ageing.
Reason for shortage	<p>The company that produces Creon is experiencing limitations in production capacity. Coupled with a high demand, this has led to intermittent shortages in the supply of Creon hard capsules. The shortages are not related to a quality defect of the product or a safety issue.</p> <p>Production capacity limitations are expected to be resolved in the second half of 2026. Until then, periodic shortages in the supply of Creon are anticipated.</p>
Member States affected	<p>The shortage affects some of the Member States where the product is marketed: Austria, Belgium, Bulgaria, Cyprus, Czechia, France, Greece, Italy, Ireland, Latvia, Luxembourg, Malta, Netherlands, Portugal, Spain and Sweden.</p> <p>This information may change. For up-to-date information about the status of a medicine shortage in a particular EU/EEA Member State, consult the national shortage register or contact the national competent authority.</p>
Monitoring of shortage	<p>EMA's SPOC working party is closely monitoring the supply situation and engaging with the marketing authorisation holder, alternative marketing authorisation holders and national authorities to identify measures to mitigate the impact of the supply shortage.</p> <p>The SPOC working party is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. Summaries of the SPOC working party meetings can be found on EMA's website.</p>
Information to healthcare professionals	<ul style="list-style-type: none">• Limitations in manufacturing capacity, combined with a high demand, have resulted in intermittent shortages in the supply of Creon hard capsules. The supply of Creon granules is not affected.• The products are authorised for the treatment of pancreatic exocrine insufficiency caused by cystic fibrosis or other conditions and the treatment of pancreatic exocrine insufficiency in the elderly.• Healthcare professionals are asked to limit prescription to the authorised indications, at the minimum effective dose, for patients already under treatment for whom it is not possible to switch to alternative. If available

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	<p>and appropriate, patients currently on treatment can be switched to a suitable alternative or lower dosage.</p> <ul style="list-style-type: none">• For additional information consult your country's shortage register or contact your national competent authority
Information to patients and carers	<ul style="list-style-type: none">• Limitations in manufacturing capacity, combined with a high demand, have resulted in periodic shortages in the supply of Creon hard capsules. There is no supply shortage of Creon granules.• These products are used to treat pancreatic exocrine insufficiency.• Your doctor has been asked to limit prescribing these products to safeguard their availability for patients.• If you are using Creon capsules, your doctor may prescribe a lower dose or switch you to a suitable alternative.• If you have any questions, speak to your doctor or pharmacist.• For additional information, consult your country's shortage register or contact your national competent authority
Status	Ongoing