IMPORTANT INFORMATION AGREED WITH THE ITALIAN MEDICINES AGENCY (AIFA)

25/10/2023

Creon® / Creonipe (pancrelipase)

Information about shortage of medicines

Creon® (pancrelipase) 10.000 Ph.Eur. units modified-release hard capsules 100 capsules (MA n. 029018064)
Creon® (pancrelipase) 25.000 Ph.Eur. units modified-release hard capsules 100 capsules (MA n. 029018049)
Creonipe® (pancrelipase) 35.000 Ph.Eur. units gastro-resistant hard capsules 100 capsules (MA n. 047002098)

Dear Healthcare Professional,

The Italian Medicines Agency, in agreement with the Marketing authorization holder/ dealer Viatris Italia s.r.l., would like toinform you of the following:

due to production problems/high demand, for medicines containing pancrelipase as active substance Creon® (pancrelipase) 10.000 Ph.Eur. units modified-release hard capsules 100 capsules (MA n. 029018064), Creon® (pancrelipase) 25.000 Ph.Eur. units modified-release hard capsules 100 capsules (MA n. 029018049) and Creonipe® (pancrelipase) 35.000 Ph.Eur. units gastro-resistant hard capsules 100 capsules (MA n. 047002098) a quota distribution is applied and this situation will presumably last until 31/12/2025.

Summary and background information

- Creon modified-release hard capsules in dosages of 10.000 Ph.Eur. units and 25.000 Ph.Eur. units is authorized for the treatment of pancreatic exocrine insufficiency caused by cystic fibrosis, chronic pancreatitis, post-pancreatectomy, total gastrectomy and partial gastric resections (BillrothI/II), ductal obstruction from neoplasms (e.g. of the pancreas or common bile duct).Pancreatic enzyme supplementation may also help in the exocrine pancreatic insufficiency of the elderly
- Creonipe gastro-resistant hard capsules 35.000 Ph. Eur. units is authorized for pancreatic enzyme replacement therapy for pancreatic exocrine insufficiency caused by cystic fibrosis or other conditions (e.g. chronic pancreatitis, pancreatectomy or pancreatic cancer).

It is estimated that quota distribution of Creon 10.000 Ph.Eur. units modified-release hard capsules (MA n. 029018064), Creon 25.000 Ph.Eur. units modified-release hard capsules (MA n. 029018064), and Creonipe 35.000 Ph.Eur. units gastro-resistant hard capsules (MA n. 047002098), will presumably last until 31/12/2025For updates on the status of shortages, please refer to the list of medicinal product shortages published on the AIFA website https://www.aifa.gov.it/web/guest/farmaci-carenti.
The supply shortage is not related to a quality defect of the product or a safety issue.

Due to discontinuous supplies, patients may not be able to find the medicine on the national territory and, consequently, therapeutic continuity may not be guaranteed.

Mitigation actions

We kindly requestyoursupport in order to:

- prescribe Creon 10.000 Ph.Eur. units and 25.000 Ph.Eur. units and Creonipe 35.000 Ph.Eur units only for authorized indications; any other use represents an off-label use and currently jeopardizes the availability of the aforementioned medicines for the target population.
- made aware patients already undergoing treatment of the above also in order to avoid hoarding phenomena;
- do not issue prescriptions for Creon 10.000 Ph.Eur. units and 25.000 Ph.Eur. units and Creonipe 35.000

Ph.Eur. units for new patients if not strictly necessary;

- reassess patients currently on treatment and switch them to a suitable alternative treatment/different dosages, if available;
- prescribe Creon 10.000 Ph.Eur. units and 25.000 Ph.Eur. units and Creonipe 35.000 Ph.Eur units only if strictly necessary, in the minimum effective dose, and if for the above-mentioned indication there are no valid therapeutic alternatives or if, for patients under treatment, it is not possible to switch to other medicines; this is to ensure that the available packages, as they are limited, are used for indications for which the medicine cannot be replaced.

Call for reporting

Adverse events, including medication errors, relatingd to Creon 10.000 Ph.Eur. units modified-release hard capsules 10000 (MA n. 029018064), Creon 25.000 Ph.Eur. units modified-release hard capsules 25.000 (MA n. 029018049) and Creonipe 35.000 Ph.Eur. units gastro-resistant hard capsules 35000 (MA n. 047002098), should be reported to Viatris Italia s.r.l. by contacting the company at the email address : pv.italia@viatris.com or telephone +39 0261246462 and to the Italian Medicines Agency through the following link https://www.aifa.gov.it/web/guest/content/segnalazioni-reazioni-avverse.

AIFA takes this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool for confirming a report favourable risk benefit under real conditions of use. Reports of Suspected Adverse Reactions from drugs must be sent to the Head of Pharmacovigilance of the relevant Structure by the operator himself. This Information Note is also published on the AIFA website (www.aifa.gov.it) whose regular consultation is recommended for the best information to professional and citizen service.

SmPCs of the products are available at the following QR code:

Company contact point

Further information on shortages and medical information can be obtained by contacting Viatris Italia s.r.l. on the toll-free number 800 95 95 00.

Viatris Italia s.r.l. will continue to provide AIFA with updates on the supply situation as soon as new information becomes available.

We sincerely apologize for this unfortunate situation and the concerns and inconvenience it may cause.

Best regards.