

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Decision extending the requirement for prior authorisation for the export of the medicinal products: Creon 25,000 300 mg gastro-resistant gel capsules 200 and Creon 35,000 420 mg gastro-resistant gel capsules 200 intended for the Belgian market.

The Minister for Public Health,

Having regard to the Law of 25 March 1964 on medicinal products for human use, Article 12f, Paragraph 2;

Having regard to the Royal Decree of 19 January 2023 implementing Article 12(f) Paragraph 2, of the law of 25 March 1964 on medicinal products, Article 4, Section 1, Section 2, Paragraph 1 and Section 3, Paragraph 1;

Having regard to the Decision of 9 February 2024, the Decision of 28 November 2024 and the Decision of 4 November 2025 submitting for export of the medicinal products Creon 5000 601.2 mg/g gastro-resistant granules 20 g, Creon 10,000 150 mg 20 and 100 gastro-resistant gel capsules, Creon 25,000 300 mg 100 gastro-resistant gel capsules, Creon 35,000 420 mg 100 and 200 gastro-resistant gel capsules intended for the Belgian market with prior authorisation;

Given the Decision of 28 November 2024 extending the submission for export of the medicinal products Creon 5000 601.2 mg/g gastro-resistant granules 20 g, Creon 10,000 150 mg 20 and 100 gastro-resistant gel capsules, Creon 25,000 300 mg 100 gastro-resistant gel capsules, Creon 35,000 420 mg 100 and 200 gastro-resistant gel capsules intended for the Belgian market with prior authorisation;

Given the Decision of 04 November 2025 extending the submission for export of the medicinal products Creon 5000 601.2 mg/g gastro-resistant granules 20 g, Creon 10,000 150 mg gastro-resistant gel capsules 20, Creon 10.000 150 mg gastro-resistant gel capsules 100, Creon 25.000 300 mg gastro-resistant gel capsules 200 and Creon 35,000 420 mg gastro-resistant gel capsules 200 intended for the Belgian market with prior authorisation;

Considering that the unavailability, within the meaning of Article 2(29), of the Royal Decree of 14 December 2006 relating to medicinal products for human use, of the medicinal products Creon 25.000 300 mg gastro-resistant gel capsules 200 and Creon 35,000 420 mg gastro-resistant gel capsules 200 until 15 January 2027 inclusive has been notified to the FAMHP;

Considering that the medicinal products Creon 25,000 300 mg gastro-resistant gel capsules 200 and Creon 35,000 420 mg gastro-resistant gel capsules 200 are used for pancreatic enzyme replacement therapy in exocrine pancreatic insufficiency due to cystic fibrosis or other conditions (e.g., chronic pancreatitis, pancreatectomy, or pancreatic cancer);

That the Creon medicinal product must be administered several times a day;

That the absence of administration of the medicinal product leads to poor digestion, malabsorption and a general deterioration of the patient's health;

Considering that no other authorised medicinal product is available for the treatment of the aforementioned conditions;

That the conditions referred to in Article 4, Section 1, of the Royal Decree of 19 January 2023 implementing Article 12f, Paragraph 2, of the Law of 25 March 1964 on medicinal products for human use are met;

DECIDES to extend the requirement for prior authorisation for the export of the medicinal products: Creon 25,000 300 mg gastro-resistant gel capsules 200 and Creon 35,000 420 mg gastro-resistant gel capsules 200, intended for the Belgian market until and including 15 January 2027.

This Decision shall enter into force on the day of its notification to wholesale distributors.

Brussels, [date]

Frank VANDENBROUCKE