Date: February 2021

IMPORTANT DRUG INFORMATION

Subject:	**Alternate Source for Active Pharmaceutical Ingredient (API) for CREON (pancrelipase) 24,000 Lipase Unit Capsules**

Audience: Healthcare professionals including pharmacists and prescribers

Dear Healthcare Professional,

The purpose of this letter is to inform you of an alternate supplier of the active ingredients known as the Active Pharmaceutical Ingredient (API) source, for CREON, a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions. CREON manufactured with the alternate source API has not yet been evaluated by the FDA for differences in efficacy or safety. Healthcare professionals should continue to assess patient symptoms associated with potential pancreatic insufficiency.

Key Information

To assure uninterrupted supply of CREON to all patients, AbbVie is coordinating with the U.S. Food and Drug Administration to use this alternate API source for AbbVie's CREON 24,000 lipase unit capsules. This alternate source API is made following the same manufacturing standards and specifications as the current API. CREON 24,000 lipase unit capsules using the alternate, unapproved API source will have the country-of-origin statement, "Product of USA," on the original bottle label, and are expected to be available to patients as early as mid-February 2021. The specific lot numbers where the alternate API source is used for CREON 24,000 lipase unit capsules can be found at www.abbviemedinfo.com at CREON/Dosage and Administration/lot number.

Prescriber Action

There is no change in the indications, dosing and administration, or safety information as described in the approved product insert (PI). There is no change to how healthcare professionals will prescribe or dispense CREON.

Healthcare professionals should continue to monitor patients treated with CREON 24,000 lipase units capsules for any changes in their symptoms of pancreatic insufficiency, treat as clinically indicated, and report to AbbVie at 1-800-633-9110. HCPs should also counsel patients using CREON 24,000 lipase units capsules to report any changes in symptoms of exocrine pancreatic

insufficiency or any adverse events they experience, together with the lot number of the drug product.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking CREON to AbbVie at 1-800-633-9110.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

Please ensure that your staff and any provider at your institution(s) who may be involved in the prescribing of CREON 24,000 lipase units capsules or monitoring or counseling patients prescribed CREON 24,000 receives a copy of this notification.

You may also contact our medical information department at 1-800-633-9110 or at www.abbviemedinfo.com if you have any questions about the information contained in this letter or the safe and effective use of CREON.

This letter is not intended as a complete description of the benefits and risks related to the use of CREON. Please refer to the enclosed full prescribing information. You can also refer to the full Prescribing Information and Medication Guide available at www.RxAbbVie.com/pdf/creon_PI.pdf.

For additional information, please call AbbVie at 1-800-633-9110 or visit www.CREON.com.

Sincerely,

Sarika Sood, MD
Therapeutic Area Lead, GI Care
US Medical Affairs, Research & Development

Enclosures: CREON Full Prescribing Information