# CREON- pancrelipase capsule, delayed release
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# AbbVie Inc.

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**
**These highlights do not include all the information needed to use CREON safely and effectively. See full prescribing information for CREON.**

**CREON (pancrelipase) delayed-release capsules, for oral use**
**Initial U.S. Approval: 2009**

## INDICATIONS AND USAGE

CREON is indicated for the treatment of exocrine pancreatic insufficiency in adult and pediatric patients. (1)

## DOSAGE AND ADMINISTRATION

Important Dosing Information (2.1)

- CREON is a mixture of enzymes including lipases, proteases, and amylases, and dosing is based on lipase units. Dosing scheme based on actual body weight or fat ingestion.
- Individualize the dosage based on clinical symptoms, the degree of steatorrhea present, and the fat content of the diet.
- Do not exceed 2,500 lipase units/kg/meal, 10,000 lipase units/kg/day, or 4,000 lipase units/g fat ingested/day in adult and pediatric patients greater than 12 months of age without further investigation. (5.1)
- The total daily dosage in adult and pediatric patients greater than 12 months of age should reflect approximately three meals plus two or three snacks per day. With each snack, administer approximately half the prescribed dose for a meal.
- Do not substitute other pancreatic enzyme products for CREON. When switching from another pancreatic enzyme product to CREON, monitor patients for clinical symptoms of exocrine pancreatic insufficiency and titrate the dosage as needed.

Recommended Dosage (2.2)

*Adult and Pediatric Patients Greater than 12 Months:* The recommended initial starting dosage is:

- 500 lipase units/kg/meal for adult and pediatric patients 4 years and older.
- 500 to 1,000 lipase units/kg/meal for adult patients with chronic pancreatitis or pancreatectomy.
- 1,000 lipase units/kg/meal for pediatric patients greater than 12 months to less than 4 years.
- Titrate the dosage to either 2,500 lipase units/kg/meal, 10,000 lipase units/kg/day, or 4,000 lipase units/g fat ingested/day. Higher dosages may be administered if documented effective by fecal fat measures or improvement of malabsorption.

*Pediatric Patients Birth to 12 Months:* The recommended dosage is 3,000 lipase units (one capsule) per 120 mL of formula or per breastfeeding.

Preparation and Administration Instructions (2.3)

- Swallow capsules whole. For patients unable to swallow intact capsule(s), the capsule contents may be sprinkled on soft acidic food (e.g., applesauce, bananas, plain Greek yogurt).
- Do not crush or chew CREON capsules or capsule contents.
- Consume sufficient liquids to ensure complete swallowing of CREON. (5.2)
- See the full prescribing information for additional information on administering to pediatric patients birth to 12 months.

## DOSAGE FORMS AND STRENGTHS

Delayed-Release Capsules (3):

- 3,000 USP units of lipase; 9,500 USP units of protease; and 15,000 USP units of amylase
- 6,000 USP units of lipase; 19,000 USP units of protease; and 30,000 USP units of amylase
- 12,000 USP units of lipase; 38,000 USP units of protease; and 60,000 USP units of amylase
- 24,000 USP units of lipase; 76,000 USP units of protease; and 120,000 USP units of amylase

- 36,000 USP units of lipase; 114,000 USP units of protease; and 180,000 USP units of amylase

**CONTRAINDICATIONS**

None (4)

**WARNINGS AND PRECAUTIONS**

- Fibrosing Colonopathy: Associated with high doses, usually over prolonged use and in pediatric patients with cystic fibrosis. Colonic stricture reported in pediatric patients less than 12 years of age with dosages exceeding 6,000 lipase units/kg/meal. Monitor during treatment for progression of preexisting disease. Do not exceed the recommended dosage, unless clinically indicated. (2.1, 5.1)
- Irritation of the Oral Mucosa: May occur due to loss of protective enteric coating on the capsule contents. (2.3, 5.2)
- Hyperuricemia: Reported with high dosages; consider monitoring blood uric acid levels in patients with gout, renal impairment, or hyperuricemia. (5.3)
- Risk of Viral Transmission: The presence of porcine viruses that might infect humans cannot be definitely excluded. (5.4)
- Hypersensitivity Reactions: Monitor patients with known reactions to proteins of porcine origin. If symptoms occur, initiate appropriate medical management; consider the risks and benefits of continued treatment. (5.5)

**ADVERSE REACTIONS**

Most Common Adverse Reactions (6.1)

*Cystic fibrosis adult and pediatric patients:*

- 7 years and older (≥4%): vomiting, dizziness, cough.
- 4 months to 6 years (6%): vomiting, irritability, decreased appetite.

*Chronic pancreatitis or pancreatectomy patients:*

- Adults (≥ 4%): hyperglycemia, hypoglycemia, abdominal pain, abnormal feces, flatulence, frequent bowel movements, nasopharyngitis.

**To report SUSPECTED ADVERSE REACTIONS, contact AbbVie Inc. at 1-800-633-9110 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**
**See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.**

**Revised: 2/2024**

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## FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

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## FULL PRESCRIBING INFORMATION

## 1 INDICATIONS AND USAGE

CREON® is indicated for the treatment of exocrine pancreatic insufficiency in adult and pediatric patients.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Important Dosing Information

CREON is a mixture of enzymes including lipases, proteases, and amylases. CREON dosing is based on lipase units.

- Use either an actual body weight or fat ingestion-based dosing scheme.
- Start at the lowest recommended dosage and individualize the dosage based on clinical symptoms, the degree of steatorrhea present, and the fat content of the diet. Changes in dosage may require an adjustment period of several days.
- Do not exceed 2,500 lipase units/kg/meal, 10,000 lipase units/kg/day, or 4,000 lipase units/g fat ingested/day in adult and pediatric patients greater than 12 months of age without further investigation *[see Warnings and Precautions (5.1)]*.
- The total daily dosage in adult and pediatric patients greater than 12 months of age should reflect approximately three meals plus two or three snacks per day. With each snack, administer approximately half the prescribed CREON dose for a meal.
- Do not substitute other pancreatic enzyme products for CREON. When switching from another pancreatic enzyme product to CREON, monitor patients for clinical symptoms of exocrine pancreatic insufficiency and titrate the dosage as needed.

## 2.2 Recommended Dosage

Adult and Pediatric Patients Greater than 12 Months of Age

The recommended oral initial starting dosage is:

- 500 lipase units/kg/meal for adult and pediatric patients 4 years of age and older.
- 500 to 1,000 lipase units/kg/meal for adult patients with chronic pancreatitis or pancreatectomy.
- 1,000 lipase units/kg/meal for pediatric patients greater than 12 months to less than 4 years of age.

If signs and symptoms of malabsorption persist, increase the dosage. Titrate to either 2,500 lipase units/kg/meal, 10,000 lipase units/kg/day, or 4,000 lipase units/gram of fat ingested/day. Higher dosages may be administered if they are documented to be effective by fecal fat measures or an improvement in signs or symptoms of malabsorption including measures of nutritional status.

Pediatric Patients Birth to 12 Months of Age

The recommended oral dosage is 3,000 lipase units per 120 mL of formula or per breast-feeding.

## 2.3 Preparation and Administration Instructions

Instruct adult and pediatric patients greater than 12 months of age, or their caregivers, of the following:

- Take CREON during meals and snacks. If a dose is missed, take the next dose with the next meal or snack.
- Swallow capsules whole.
- For patients who are unable to swallow intact capsules, carefully open the capsules and sprinkle the entire contents on a small amount of acidic soft food with a pH of 4.5 or less (e.g., applesauce, bananas, plain Greek yogurt). Consume the entire mixture immediately.
- Do not crush or chew CREON capsules or capsule contents.
- Consume sufficient liquids (water or juice) to ensure complete swallowing of CREON *[see Warnings and Precautions (5.2)]*.

Instruct caregivers of pediatric patients birth to 12 months of age of the following:

- Immediately prior to each breast-feeding session or each administration of 120 mL of formula, carefully open one CREON capsule (containing 3,000 USP units of lipase) and administer the entire contents using one of the following two methods:
  - Sprinkle on a small amount of acidic soft food with a pH of 4.5 or less (e.g., applesauce, bananas, plain Greek yogurt) being careful not to crush the capsule contents. The entire mixture should be given to the infant immediately.
  - Sprinkle the capsule contents directly into the infant’s mouth.

- Immediately administer additional breast milk or formula after CREON to ensure complete swallowing of the capsule contents.
- Do not mix CREON capsule contents directly into a bottle of breast milk or formula.
- Do not crush CREON capsule contents, and visually inspect the infant’s mouth to ensure that no drug is retained in the mouth *[see Warnings and Precautions (5.2)]*.
- If a dose is missed, administer the next dose with the next feeding.

## 3 DOSAGE FORMS AND STRENGTHS

Delayed-release capsules are available in the following strengths:

- 3,000 USP units of lipase; 9,500 USP units of protease; and 15,000 USP units of amylase in a two-piece capsule with a white opaque cap imprinted with “CREON 1203” and a white opaque body.
- 6,000 USP units of lipase; 19,000 USP units of protease; and 30,000 USP units of amylase in a two-piece capsule with an orange opaque cap imprinted with “CREON 1206” and a blue opaque body.
- 12,000 USP units of lipase; 38,000 USP units of protease; and 60,000 USP units of amylase in a two-piece capsule with a brown opaque cap imprinted with “CREON 1212” and a colorless transparent body.
- 24,000 USP units of lipase; 76,000 USP units of protease; and 120,000 USP units of amylase in a two-piece capsule with an orange opaque cap imprinted with “CREON 1224” and a colorless transparent body.
- 36,000 USP units of lipase; 114,000 USP units of protease; and 180,000 USP units of amylase in a two-piece capsule with a blue opaque cap imprinted with “CREON 1236” and a colorless transparent body.

## 4 CONTRAINDICATIONS

None.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Fibrosing Colonopathy

Fibrosing colonopathy has been reported following treatment with pancreatic enzyme products. Fibrosing colonopathy is a rare, serious adverse reaction initially described in association with use of high-dose pancreatic enzyme products, usually over a prolonged period of time and most commonly reported in pediatric patients with cystic fibrosis. Pancreatic enzyme products exceeding 6,000 lipase units/kg/meal have been associated with colonic stricture, a complication of fibrosing colonopathy, in pediatric patients less than 12 years of age. The underlying mechanism of fibrosing colonopathy remains unknown.

If there is history of fibrosing colonopathy, monitor patients during treatment with CREON because some patients may be at risk of progressing to colonic stricture formation. It is uncertain whether regression of fibrosing colonopathy occurs. Do not exceed the recommended dosage of either 2,500 lipase units/kg/meal, 10,000 lipase units/kg/day, or 4,000 lipase units/g fat ingested/day in adult and pediatric patients greater than 12 months of age without further investigation. Higher dosages may be administered if they are documented to be effective by fecal fat measures or an improvement in signs or symptoms of malabsorption including measures of nutritional status. Patients receiving dosages higher than 6,000 lipase units/kg/meal should be frequently monitored for symptoms of fibrosing colonopathy and the dosage decreased or titrated downward to a lower range if clinically appropriate *[see Dosage and Administration (2.1)]*.

### 5.2 Irritation of the Oral Mucosa

Crushing or chewing CREON capsules or mixing the capsule contents in foods having a pH greater than 4.5 can disrupt the protective enteric coating on the capsule contents and result in early release of enzymes, irritation of the oral mucosa, and/or loss of enzyme activity.

Instruct the patient or caregiver of the following:

- Swallow capsules whole. For patients who cannot swallow the capsules whole, the capsules can be opened, and the contents sprinkled in a small amount of acidic soft food with a pH of 4.5 or less (e.g., applesauce, bananas, plain Greek yogurt).
- Do not crush or chew CREON capsules or capsule contents.
- Consume sufficient liquids (juice, water, breast milk, or formula) immediately following administration of CREON to ensure complete swallowing.
- Visually inspect the mouth of pediatric patients less than 12 months of age and of patients who are unable to swallow intact capsules to ensure no drug is retained in the mouth and irritation of the oral mucosa has not occurred *[see Dosage and Administration (2.3)]*.

### 5.3 Hyperuricemia

Pancreatic enzyme products contain purines that may increase blood uric acid levels. High dosages have been associated with hyperuricosuria and hyperuricemia *[see Overdosage (10)].* Consider monitoring blood uric acid levels in patients with gout, renal impairment, or hyperuricemia during treatment with CREON.

### 5.4 Risk of Viral Transmission

CREON is sourced from pancreatic tissue from swine used for food consumption. Although the risk that CREON will transmit an infectious agent to humans has been reduced by testing for certain viruses during manufacturing and by inactivating certain viruses during manufacturing, there is a theoretical risk for transmission of viral disease, including diseases caused by novel or unidentified viruses. Thus, the presence of porcine viruses that might infect humans cannot be definitely excluded. However, no cases of transmission of an infectious illness associated with the use of porcine pancreatic extracts have been reported.

### 5.5 Hypersensitivity Reactions

Severe hypersensitivity reactions including anaphylaxis, asthma, hives, and pruritus have been reported with pancreatic enzyme products *[see Adverse Reactions (6.2)]*. If symptoms occur, initiate appropriate medical management.

Monitor patients with a known hypersensitivity reaction to proteins of porcine origin for hypersensitivity reactions during treatment with CREON. The risks and benefits of continued CREON treatment in patients with severe hypersensitivity reactions should be taken into consideration with the overall clinical needs of the patient.

## 6 ADVERSE REACTIONS

The following serious or otherwise important adverse reactions are described elsewhere in the labeling:

- Fibrosing Colonopathy *[see Warnings and Precautions (5.1)]*
- Irritation of the Oral Mucosa *[see Warnings and Precautions (5.2)]*
- Hyperuricemia *[see Warnings and Precautions (5.3)]*
- Risk of Viral Transmission *[see Warnings and Precautions (5.4)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.5)]*

### 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to CREON in 92 patients: 67 patients aged 4 months to 43 years with exocrine pancreatic insufficiency due to cystic fibrosis (Studies 1, 2, and 3) and 25 adults with exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy (Study 4) *[see Use in Specific Populations (8.4) and Clinical Studies (14.1, 14.2)]*.

Exocrine Pancreatic Insufficiency Due to Cystic Fibrosis in Adult and Pediatric Patients

*Adult and Pediatric Patients 7 Years of Age and Older*

The most common adverse reactions, reported in at least 2 CREON-treated patients (greater than or equal to 4%) and at a higher rate than in placebo-treated patients in Studies 1 and 2, are shown in Table 1.

**Table 1: Adverse Reactions* in Clinical Trials of Adult and Pediatric Patients 7 Years of Age and Older with Exocrine Pancreatic Insufficiency due to Cystic Fibrosis (Studies 1 and 2)**

| Adverse Reaction | CREON N = 49 n (%) | Placebo N = 47 n (%) |
|---|---|---|
| Vomiting | 3 (6%) | 1 (2%) |
| Dizziness | 2 (4%) | 1 (2%) |
| Cough | 2 (4%) | 0 (0%) |

* Reported in at least 2 CREON-treated patients (greater than or equal to 4%) and at a higher rate than placebo-treated patients.

In Study 1, one patient experienced duodenitis and gastritis of moderate severity 16 days after completing treatment with CREON. Transient neutropenia without clinical sequelae was observed as an abnormal laboratory finding in one patient receiving CREON and a macrolide antibiotic.

*Pediatric Patients 4 Months to 6 Years of Age*

Adverse reactions reported in 18 CREON-treated pediatric patients aged 4 months to 6 years in Study 3 were vomiting, irritability, and decreased appetite, each occurring in 6% of patients *[see Use in Specific Populations (8.4)]*.

Exocrine Pancreatic Insufficiency Due to Chronic Pancreatitis or Pancreatectomy in Adults

Adverse reactions reported in at least 1 adult CREON-treated patient (greater than or equal to 4%) and at a higher rate than in placebo-treated patients in Study 4 is shown in Table 2.

**Table 2: Adverse Reactions* in a Clinical Trial of Adult Patients with Exocrine Pancreatic Insufficiency Due to Chronic Pancreatitis or Pancreatectomy (Study 4)**

| Adverse Reaction | CREON N = 25 n (%) | Placebo N = 29 n (%) |
|---|---|---|
| Hyperglycemia | 2 (8%) | 2 (7%) |
| Hypoglycemia | 1 (4%) | 1 (3%) |
| Abdominal Pain | 1 (4%) | 1 (3%) |
| Abnormal Feces | 1 (4%) | 0 (0%) |
| Flatulence | 1 (4%) | 0 (0%) |
| Frequent Bowel Movements | 1 (4%) | 0 (0%) |
| Nasopharyngitis | 1 (4%) | 0 (0%) |

* Reported in at least 1 CREON-treated patient (greater than or equal to 4%) and at a higher rate than placebo-treated patients.

### 6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of CREON or other pancreatic enzyme products. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Eye Disorders*
- blurred vision

*Gastrointestinal Disorders*
- fibrosing colonopathy and distal intestinal obstruction syndrome
- abdominal pain, diarrhea, flatulence, constipation, and nausea

*Immune System Disorders*
- anaphylaxis, asthma, hives, and pruritus

*Investigations*
- asymptomatic elevations of liver enzymes

*Musculoskeletal System*
- myalgia, muscle spasm

*Skin and Subcutaneous Tissue Disorders*
- urticaria and rash

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary

Published data from case reports with pancrelipase use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Pancrelipase is minimally absorbed systematically; therefore, maternal use is not expected to result in fetal exposure to the drug. Animal reproduction studies have not been conducted with pancrelipase.

The background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

### 8.2 Lactation

Risk Summary

There are no data on the presence of pancrelipase in either human or animal milk, the effects on the breastfed infant or the effects on milk production. Pancrelipase is minimally absorbed systemically following oral administration; therefore, maternal use is not expected to result in clinically relevant exposure of breastfed infants to the drug. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for CREON and any potential adverse effects on the breastfed infant from CREON or from the underlying maternal condition.

### 8.4 Pediatric Use

The safety and effectiveness of CREON for the treatment of exocrine pancreatic insufficiency have been established in pediatric patients.

Use of CREON for this indication is supported by two adequate and well-controlled trials in adult and pediatric patients 12 years and older (Study 1) and in pediatric patients 7 to 11 years of age (Study 2) along with supportive data from an open-label, single-arm, study in 18 pediatric patients 4 months to six years of age (Study 3). All three study populations consisted of patients with exocrine pancreatic insufficiency due to cystic fibrosis. The safety in pediatric patients 7 years of age and older in Studies 1 and 2 were similar to that observed adult patients *[see Adverse Reactions (6.1) and Clinical Studies (14)]*.

In Study 3, patients received their usual pancreatic enzyme replacement therapy (mean dose of 7,000 lipase units/kg/day for a mean duration of 18.2 days) followed by CREON (mean dose of 7,500 lipase units/kg/day for a mean duration of 12.6 days). The mean daily fat intake was 48 grams during treatment with usual pancreatic enzyme replacement therapy and 47 grams during treatment with CREON. Adverse reactions that occurred in patients during treatment with CREON in Study 3 were vomiting, irritability, and decreased appetite *[see Adverse Reactions (6.1)]*.

Dosages exceeding 6,000 lipase units/kg/meal have been reported postmarketing to be associated with fibrosing colonopathy and colonic strictures in pediatric patients less than 12 years of age. If there is a history of fibrosing colonopathy, monitor patients during treatment with CREON because some patients may be at risk of progressing to

stricture formation. Do not exceed the recommended dosage of either 2,500 lipase units/kg/meal, 10,000 lipase units/kg/day, or 4,000 lipase units/g fat ingested/day in pediatric patients greater than 12 months of age without further investigation *[see Dosage and Administration (2.2) and Warnings and Precautions (5.1)]*.

Crushing or chewing CREON capsules or mixing the capsule contents in foods having a pH greater than 4.5 can disrupt the protective enteric coating on the capsule contents and result in early release of enzymes, irritation of the oral mucosa, and/or loss of enzyme activity. Instruct the patient or caregiver of the following: consume sufficient liquids (juice, water, breast milk, or formula) to ensure complete swallowing, and visually inspect the mouth of pediatric patients less than 12 months of age to ensure no drug is retained in the mouth and irritation of the oral mucosa has not occurred *[see Dosage and Administration (2.3) and Warnings and Precautions (5.2)].*

### 8.5 Geriatric Use

Clinical studies of CREON did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between patients aged 65 years and over and younger adult patients.

## 10 OVERDOSAGE

Chronic high dosages of pancreatic enzyme products have been associated with fibrosing colonopathy and colonic strictures *[see Warnings and Precautions (5.1)]*. High dosages of pancreatic enzyme products have been associated with hyperuricosuria and hyperuricemia *[see Warnings and Precautions (5.3)]*.

## 11 DESCRIPTION

Pancrelipase is a pancreatic enzyme product consisting of a mixture of enzymes including lipases, proteases, and amylases and is an extract derived from porcine pancreatic glands. The enteric-coated spheres in CREON are formulated to release pancreatic enzymes at an approximate pH of 5.5 or greater.

CREON (pancrelipase) delayed-release capsules are for oral administration, include a two-piece shell containing tan-colored enteric-coated spheres (0.71 mm to 1.60 mm in diameter), and are available as follows:

3,000 USP units of lipase; 9,500 USP units of protease; and 15,000 USP units of amylase; delayed-release capsules with shells that contain hypromellose and titanium dioxide, and that also may contain carrageenan and potassium chloride.

6,000 USP units of lipase; 19,000 USP units of protease; and 30,000 USP units of amylase; delayed-release capsules with shells that may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, FD&C Blue No. 1, and FD&C Blue No. 2, red iron oxide, and yellow iron oxide.

12,000 USP units of lipase; 38,000 USP units of protease; and 60,000 USP units of amylase; delayed-release capsules with shells that may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, black iron oxide, red iron oxide, and yellow iron oxide.

24,000 USP units of lipase; 76,000 USP units of protease; and 120,000 USP units of amylase; delayed-release capsules with shells that may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, red iron oxide, and yellow iron oxide.

36,000 USP units of lipase; 114,000 USP units of protease; and 180,000 USP units of amylase; delayed-release capsules with shells that may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, FD&C Blue No. 1, and FD&C Blue No. 2.

CREON (pancrelipase) delayed-release capsules include the following inactive ingredients: cetyl alcohol, dimethicone, hypromellose phthalate, polyethylene glycol, and triethyl citrate.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Pancreatic enzyme products contain a mixture of lipases, proteases, and amylases that catalyze the hydrolysis of fats to monoglyceride, glycerol and free fatty acids, proteins into peptides and amino acids, and starches into dextrins and short chain sugars such as maltose and maltriose in the duodenum and proximal small intestine, thereby acting like digestive enzymes physiologically secreted by the pancreas.

### 12.2 Pharmacodynamics

For patients consuming a high fat diet in the clinical trials, the coefficient of fat absorption (CFA) was higher in patients who received CREON compared to the placebo treatment group, indicating improved fat absorption *[see Clinical Studies (14.1,14.2)]*.

### 12.3 Pharmacokinetics

Following oral administration, the lipases, proteases, and amylases released from CREON are not absorbed from the gastrointestinal tract in appreciable amounts.

Drug Interactions

The lipases, proteases, and amylases of CREON are not substrates of CYP enzymes or transporters. CYP enzymes or transporters mediated drug interactions are not expected.

## 14 CLINICAL STUDIES

### 14.1 Exocrine Pancreatic Insufficiency Due to Cystic Fibrosis

Adult and Pediatric Patients

Studies 1 and 2 were randomized, double-blind, placebo-controlled, crossover studies in 49 patients, aged 7 to 43 years, with exocrine pancreatic insufficiency due to cystic fibrosis.

- Study 1 included patients aged 12 to 43 years (n = 32). The final analysis population was limited to 29 patients; 3 patients were excluded due to protocol deviations.

- Study 2 included patients aged 7 to 11 years (n = 17). The final analysis population was limited to 16 patients; 1 patient withdrew consent prior to stool collection during treatment with CREON.

In each study, patients were randomized to receive CREON at a dose of 4,000 lipase units/g fat ingested/day or matching placebo for 5 to 6 days of treatment, followed by crossover to the alternate treatment for an additional 5 to 6 days. All patients consumed a high-fat diet (greater than or equal to 90 grams of fat per day, 40% of daily calories derived from fat) during the treatment periods.

*Coefficient of Fat Absorption Endpoint and Results*

The primary efficacy endpoint was the coefficient of fat absorption (CFA) in CREON and placebo treatment groups. The coefficient of fat absorption (CFA) was determined by a 72-hour stool collection during both treatments, when both fat excretion and fat ingestion were measured. Each patient's CFA during placebo treatment was used as their no-treatment CFA value.

In Study 1, mean CFA was 89% with CREON treatment compared to 49% with placebo treatment. The mean difference in CFA was 41 percentage points in favor of CREON treatment with 95% CI: (34, 47) and $p<0.001$.

In Study 2, mean CFA was 83% with CREON treatment compared to 47% with placebo treatment. The mean difference in CFA was 35 percentage points in favor of CREON treatment with 95% CI: (27, 44) and $p<0.001$.

Subgroup analyses of the CFA results in Studies 1 and 2 showed that mean change in CFA with CREON treatment was greater in patients with lower no-treatment (placebo) CFA values than in patients with higher no-treatment (placebo) CFA values. There were no differences in response to CREON by age or biological sex, with similar responses to CREON observed in male and female patients, and in younger (under 18 years of age) and older patients.

*Coefficient of Nitrogen Absorption Endpoint and Results*

The coefficient of nitrogen absorption (CNA) was determined by a 72-hour stool collection during both treatments, when nitrogen excretion was measured and nitrogen ingestion from a controlled diet was estimated (based on the assumption that proteins contain 16% nitrogen). Each patient's CNA during placebo treatment was used as their no-treatment CNA value.

- In Study 1, mean CNA was 86% with CREON treatment compared to 49% with placebo treatment. The mean difference in CNA was 37 percentage points in favor of CREON treatment with 95% CI: (31, 42) and $p<0.001$.
- In Study 2, mean CNA was 80% with CREON treatment compared to 45% with placebo treatment. The mean difference in CNA was 35 percentage points in favor of CREON treatment with 95% CI: (26, 45) and $p<0.001$.

### 14.2 Exocrine Pancreatic Insufficiency Due to Chronic Pancreatitis or Pancreatectomy

A randomized, double-blind, placebo-controlled, parallel group study was conducted in 54 adult patients, aged 32 to 75 years, with exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy (Study 4). The final analysis population was limited to 52 patients; 2 patients were excluded due to protocol violations. Ten patients

had a history of pancreatectomy (7 were treated with CREON). In this study, patients received placebo for 5 days (run-in period), followed by pancreatic enzyme replacement therapy as directed by the investigator for 16 days; this was followed by randomization to CREON or matching placebo for 7 days of treatment (double-blind period). Only patients with CFA less than 80% in the run-in period were randomized to the double-blind period. All patients were to consume a high-fat diet (greater than or equal to 100 grams of fat/day) during the treatment period. The dosage of CREON during the double-blind period was 72,000 lipase units per main meal (3 main meals) and 36,000 lipase units per snack (2 snacks) [approximately 1,000 lipase units/kg/meal]. The mean exposure to CREON during this study was 7 days in the 25 patients that received CREON.

*Coefficient of Fat Absorption Endpoint and Results*

The CFA was determined by a 72-hour stool collection during the run-in and double-blind treatment periods, when both fat excretion and fat ingestion were measured. The mean change in CFA from the run-in period to the end of the double-blind period in the CREON and placebo groups is shown in Table 3.

**Table 3: Change in Coefficient of Fat Absorption in Adults with Exocrine Pancreatic Insufficiency Due to Chronic Pancreatitis and Pancreatectomy (Study 4)**

| | **CREON N = 24** | **Placebo N = 28** |
|---|---|---|
| **CFA [%]** | | |
| Run-in Period (Mean, SD) | 54 (19) | 57 (21) |
| End of Double-Blind Period (Mean, SD) | 86 (6) | 66 (20) |
| **Change in CFA * [%]** | | |
| Run-in Period to End of Double-Blind Period (Mean, SD) | 32 (18) | 9 (13) |
| Treatment Difference (95% CI) | 21 (14, 28) | |
| *p<0.0001 | | |

Subgroup analyses of the CFA results showed that mean change in CFA was greater in patients with lower run-in period CFA values than in patients with higher run-in period CFA values. Only 1 of the patients with a history of total pancreatectomy was treated with CREON in the study. That patient had a CFA of 26% during the run-in period and a CFA of 73% at the end of the double-blind period. The remaining 6 patients with a history of partial pancreatectomy treated with CREON on the study had a mean CFA of 42% during the run-in period and a mean CFA of 84% at the end of the double-blind period.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

CREON (pancrelipase) delayed-release capsules, containing tan-colored enteric-coated pancrelipase spheres, are supplied as follows:

| **Strength** | **Description** | **Supplied As** | **NDC Number** |
|---|---|---|---|
| 3,000 USP units | | | |

| | | | |
|---|---|---|---|
| of lipase; 9,500 USP units of protease; 15,000 USP units of amylase | Two-piece hypromellose capsule, white opaque cap imprinted “CREON 1203”, white opaque body | Bottles of 70 | 0032-0045-70 |
| | | | 0032-1203-70 |
| 6,000 USP units of lipase; 19,000 USP units of protease; 30,000 USP units of amylase | Two-piece hypromellose capsule, orange opaque cap imprinted “CREON 1206”, blue opaque body | Bottles of 100 | 0032-0046-70 |
| | Two-piece gelatin capsule, orange opaque cap imprinted “CREON 1206”, blue opaque body | Bottles of 100 | 0032-1206-01 |
| | | Bottles of 250 | 0032-1206-07 |
| 12,000 USP units of lipase; 38,000 USP units of protease; 60,000 USP units of amylase | Two-piece hypromellose capsule, brown opaque cap imprinted “CREON 1212”, colorless transparent body | Bottles of 100 | 0032-0047-70 |
| | Two-piece gelatin capsule, brown opaque cap imprinted “CREON 1212”, colorless transparent body | Bottles of 100 | 0032-1212-01 |
| | | Bottles of 250 | 0032-1212-07 |
| 24,000 USP units of lipase; 76,000 USP units of protease; 120,000 USP units of amylase | Two-piece hypromellose capsule, orange opaque cap imprinted “CREON 1224”, colorless transparent body | Bottles of 100 | 0032-2636-01 |
| | | Bottles of 240 | 0032-2636-70 |
| | Two-piece gelatin capsule, orange opaque cap imprinted “CREON 1224”, colorless transparent body | Bottles of 100 | 0032-1224-01 |
| | | Bottles of 250 | 0032-1224-07 |
| 36,000 USP units of lipase; 114,000 USP | Two-piece hypromellose capsule, blue | Bottles | 0032-2637- |

| | | | |
|---|---|---|---|
| units of protease; 180,000 USP units of amylase | opaque cap imprinted “CREON 1236”, colorless transparent body | Bottles of 100 | 0032-2637-01 |
| | | Bottles of 240 | 0032-2637-70 |
| | Two-piece gelatin capsule, blue opaque cap imprinted “CREON 1236”, colorless transparent body | Bottles of 100 | 0032-3016-13 |
| | | Bottles of 250 | 0032-3016-28 |

Storage and Handling

- Store CREON at room temperature, 15°C to 25°C (59°F to 77°F), and protect from moisture. Temperature excursions are permitted between 25°C to 40°C (77°F to 104°F) for up to 30 days. Discard CREON if exposed to higher temperature and moisture conditions higher than 70%.
- *After opening, keep bottle tightly closed between uses to protect from moisture. Keep the desiccant in the bottle if present.*
- Store and dispense CREON in the original container.

## 17 PATIENT COUNSELING INFORMATION

Advise the patient or caregiver to read the FDA-approved patient labeling (Medication Guide).

Fibrosing Colonopathy

Advise the patient or caregiver that fibrosing colonopathy has been reported with high dosages of pancreatic enzyme products, usually with use over a prolonged period of time and in pediatric patients with cystic fibrosis. Colonic stricture has been reported in pediatric patients less than 12 years of age. Advise patients and caregivers that if signs and symptoms of colon stricture formation occur (e.g., stomach area (abdominal) pain, bloating, trouble passing stool (constipation), nausea, vomiting, diarrhea) to immediately contact their healthcare provider *[see Warnings and Precautions (5.1)]*.

Hyperuricemia

Advise the patient or caregiver that hyperuricemia may occur in patients with gout or renal impairment and to contact the healthcare provider if they experience pain, stiffness, redness or swelling of their joints *[see Warnings and Precautions (5.3)].*

Hypersensitivity Reactions

Inform the patient or caregiver that severe hypersensitivity reactions, including anaphylaxis, asthma, hives, and pruritus, have been reported with use of pancreatic enzyme products. Seek medical attention if signs or symptoms of a hypersensitivity reaction develop *[see Warnings and Precautions (5.5)]*.

Dosage

Advise the patient or caregiver to take or administer CREON as prescribed, and to

contact the healthcare provider if signs and symptoms of malabsorption persist *[see Dosage and Administration (2.2)]*.

Administration

Instruct the patient or caregiver as follows:

- Take CREON during meals and snacks.
- Swallow capsules whole.
- For adult and pediatric patients unable to swallow intact capsules, the capsule contents may be sprinkled on a small amount of soft acidic food with a pH of 4.5 or less (e.g., applesauce, bananas, plain Greek yogurt). For pediatric patients birth to 12 months of age, CREON capsules can also be opened, and the capsule contents sprinkled directly into the infant's mouth.
- Consume sufficient liquids (juice, water, breast milk, or formula) and visually inspect an infant's mouth to ensure complete swallowing of CREON capsules or capsule contents *[see Warnings and Precautions (5.2)]*.
- Do not crush or chew CREON capsules or capsule contents.
- Do not mix the CREON capsule contents directly into a bottle of breast milk or formula.

Storage

Instruct the patient or caregiver as follows:

- Keep CREON in a dry place and protect from heat.
- After opening, keep the bottle tightly closed between uses to protect from moisture.
- Keep CREON in the original container.
- If there is a desiccant packet in the bottle, keep it in the bottle. Do not eat or throw away the desiccant.



CREON® is a registered trademark of AbbVie Products LLC.

Manufactured by:

AbbVie Inc.

North Chicago, IL 60064, U.S.A.

US License Number 1889

20082735 February, 2024

**MEDICATION GUIDE**
**CREON® (krē ˊŏn)**
**(pancrelipase)**
**delayed-release capsules, for oral use**

**What is the most important information I should know about CREON?**
CREON may increase your chance of having a rare bowel disorder called fibrosing colonopathy especially if taken at a high dose for a long time in children with cystic fibrosis. This condition is serious and may require surgery. The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you. **Call your healthcare provider right away if you have any**

**unusual or severe:**

- stomach area (abdominal) pain
- bloating
- trouble passing stool (having bowel movements)
- nausea, vomiting, or diarrhea

Take CREON exactly as prescribed. **Do not** take more or less CREON than directed by your healthcare provider.

**What is CREON?**

CREON is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes.
CREON contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas.
CREON is safe and effective in adults and children.

**Before you take CREON, tell your healthcare provider about all your medical conditions, including if you:**

- are allergic to pork (pig) products.
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy).
- have gout, kidney disease, or high blood uric acid (hyperuricemia).
- have trouble swallowing capsules.
- have any other medical condition.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if CREON passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take CREON.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

**How should I take CREON?**

- **Take CREON exactly as your healthcare provider tells you.** Contact your healthcare provider if you continue to have signs and symptoms of malabsorption (not absorbing nutrients from food) such as abdominal pain, abdominal distention, bloating, fatty stools, or weight loss. Your dose may need to be changed.
- You should not switch CREON with any other pancreatic enzyme product without first talking to your healthcare provider.
- Do not take more capsules in a day than the number your healthcare provider tells you to take (total daily dose).
- **Always take CREON with a meal or snack** and enough liquid (water, juice, breast milk, or formula) to swallow CREON completely. If you eat a lot of meals or snacks in a day, be careful not to go over your total daily dose.
- Your healthcare provider may change your dose based on the amount of fatty foods you eat or based on your weight.
- **CREON capsules should be swallowed whole. Do not crush or chew CREON capsules or its contents, and do not hold the capsule or capsule contents in your mouth.** Crushing, chewing or holding the CREON capsules in your mouth may cause irritation in your mouth or change the way CREON works in your body.

**Giving CREON to Adults and Children Older than 12 Months of Age**

- Swallow CREON capsules whole without crushing or chewing them.
- If you have trouble swallowing capsules:
  - Carefully open the capsules and sprinkle the entire contents on small amounts of acidic soft food such as applesauce, bananas, or plain Greek yogurt. Ask your healthcare provider about other foods you can use.
  - Mix the capsule contents with the soft food. Do not crush the contents.
  - Swallow the mixture right away. Do not save it for later use.

- Drink enough water or juice right away to make sure the medicine is swallowed completely.
- If you forget to take CREON, call your healthcare provider or wait until your next meal and take your usual number of capsules. Take your next dose at your usual time. **Do not make up for missed doses.**

**Giving CREON to Infants (Children from Birth up to 12 Months of Age)**

- Give CREON right before each breastfeeding or feeding formula.
- Do not mix CREON capsule contents directly into formula or breast milk.
- Carefully open the capsule and do one of the following:
  - Sprinkle the entire contents directly into your child's mouth **or**
  - Mix the entire contents in a small amount of acidic soft food such as applesauce, bananas, or plain Greek yogurt as described in the previous section. These foods should be the kind found in baby food jars that you buy at the store, or other food recommended by your healthcare provider. Give the mixture to your child right away. Do not save it for later use.

- Give your child additional breast milk or formula **right after** CREON to completely swallow the medicine. Look in your child's mouth to make sure that it was all swallowed.
- If a dose is missed give the next dose with the next feeding.

**What are the possible side effects of CREON?**
**CREON may cause serious side effects, including:**

- See "**What is the most important information I should know about CREON?**"
- **Irritation of the inside of your mouth.** This can happen if CREON is not swallowed completely.
- **Increase in blood uric acid levels (hyperuricemia).** This may happen in people with gout, kidney problems, or those who take high doses of pancrelipase, the active ingredient in CREON. Call your healthcare provider if you have pain, stiffness, redness or swelling of your joints.
- **Severe allergic reactions.** Severe allergic reactions have happened in people taking pancreatic enzyme products like CREON. Stop taking CREON and get emergency treatment right away if you have any of these symptoms: trouble with breathing, skin rashes, swollen lips, or itching.

**The most common side effects of CREON include:**

- Blood sugar increase (hyperglycemia) or decrease (hypoglycemia)
- Pain in your stomach (abdominal area)

- Frequent or abnormal bowel movements
- Gas
- Vomiting
- Dizziness
- Sore throat and cough

**Other Possible Side Effects:**
CREON and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs.
Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
These are not all the possible side effects of CREON. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**
You may also report side effects to AbbVie Inc. at 1-800-633-9110.

**How should I store CREON?**
- Store CREON at room temperature between 59°F to 77°F (15°C to 25°C). Avoid heat.
- You may store CREON at a temperature between 77°F to 104°F (25°C to 40°C) for up to 30 days. Throw away any CREON stored at these temperatures for more than 30 days.
- Keep CREON in a dry place and in the original container.
- After opening the bottle, keep it closed tightly between uses to protect from moisture. If there is a moisture-absorbing packet (desiccant) in the bottle, keep it in the bottle. Do not eat it or throw it away.

**Keep CREON and all medicines out of the reach of children.**

**General information about the safe and effective use of CREON.**
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CREON for a condition for which it was not prescribed. Do not give CREON to other people to take, even if they have the same symptoms you have. It may harm them.
You can ask your healthcare provider or pharmacist for information about CREON that is written for healthcare professionals.

**What are the ingredients in CREON?**
**Active Ingredient:** lipase, protease, amylase
**Inactive Ingredients:** cetyl alcohol, dimethicone, hypromellose phthalate, polyethylene glycol, and triethyl citrate.
The shells for the CREON 3,000 USP units of lipase strength capsules contain hypromellose and titanium dioxide. They also may contain carrageenan and potassium chloride.
The shells of the CREON 6,000 USP units of lipase strength capsules may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, FD&C Blue No. 1, FD&C Blue No. 2, red iron oxide, and yellow iron oxide.
The shells of the CREON 12,000 USP units of lipase strength capsules may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, black iron oxide, red iron oxide, and yellow iron oxide.
The shells for the CREON 24,000 USP units of lipase strength capsules may contain

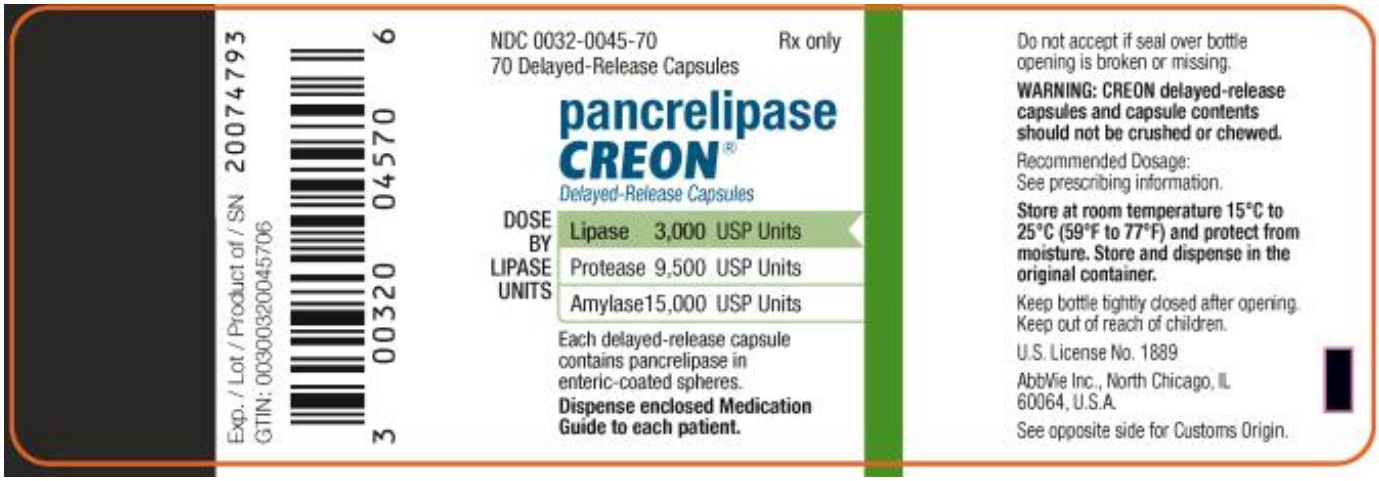
gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, red iron oxide, and yellow iron oxide.
The shells of the CREON 36,000 USP units of lipase strength capsules may contain gelatin, hypromellose, carrageenan, potassium chloride, sodium lauryl sulfate, titanium dioxide, FD&C Blue No. 1, and FD&C Blue No. 2.
Manufactured by:
AbbVie Inc.
North Chicago, IL 60064, U.S.A.
US License Number 1889


For more information, go to www.creon-us.com or call toll-free (1-800-633-9110).

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Revised: 2/2024

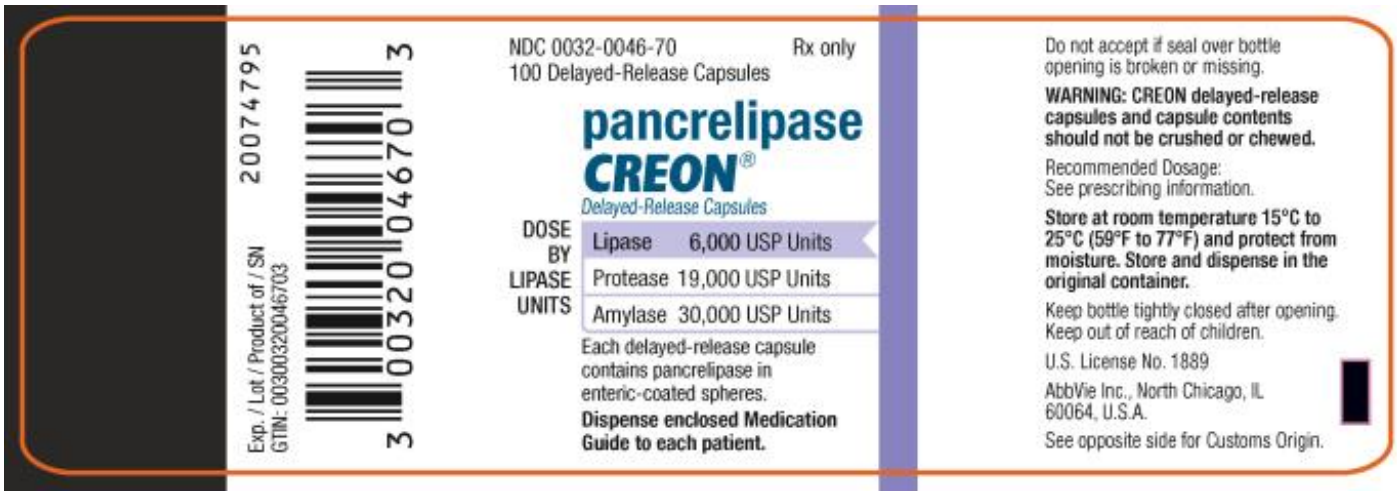
20082735

NDC 0032-0045-70
70 Delayed-Release Capsules
Rx only
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 3,000 USP Units
Protease 9,500 USP Units
Amylase 15,000 USP Units
Each delayed-release capsule contains
pancrelipase in enteric-coasted spheres.
**Dispense enclosed Medication Guide to each patient.**

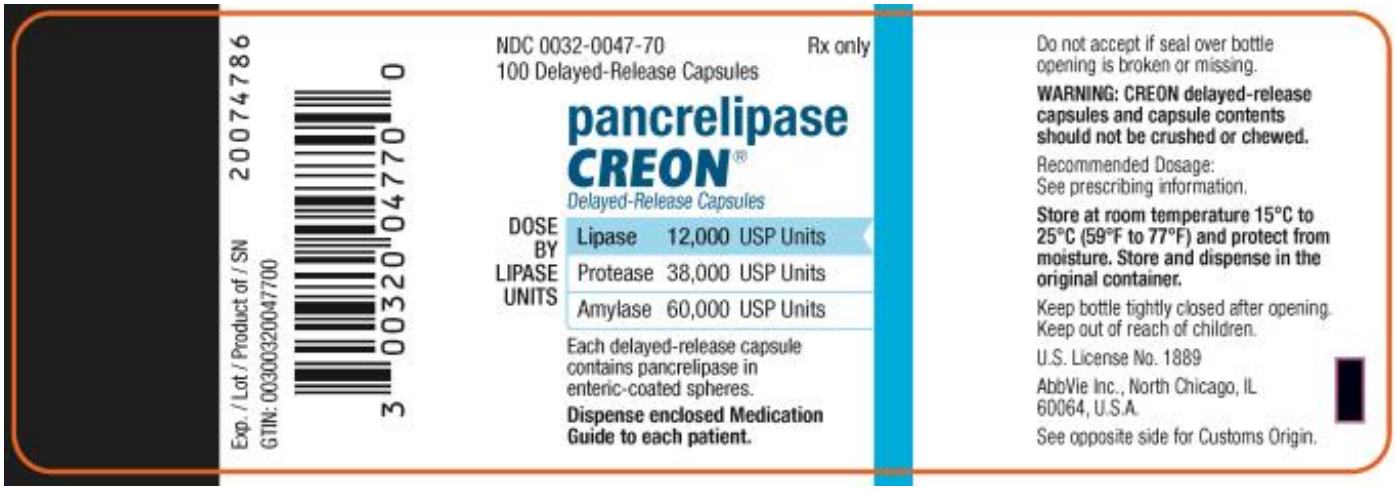



NDC 0032-0046-70
100 Delayed-Release Capsules
Rx only

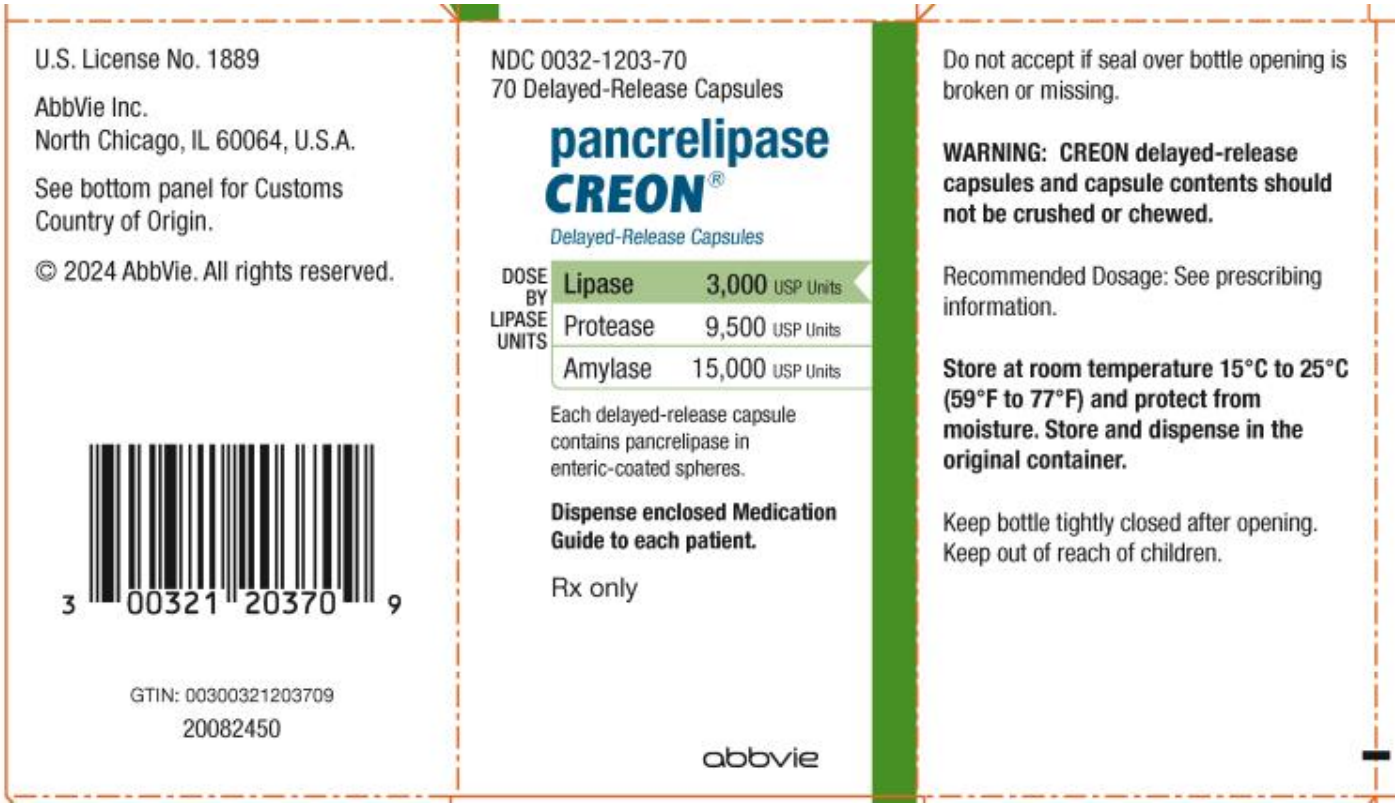
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 6,000 USP Units
Protease 19,000 USP Units
Amylase 30,000 USP Units
Each delayed-release capsule contains
pancrelipase in enteric-coasted spheres.
**Dispense enclosed Medication Guide to each patient.**



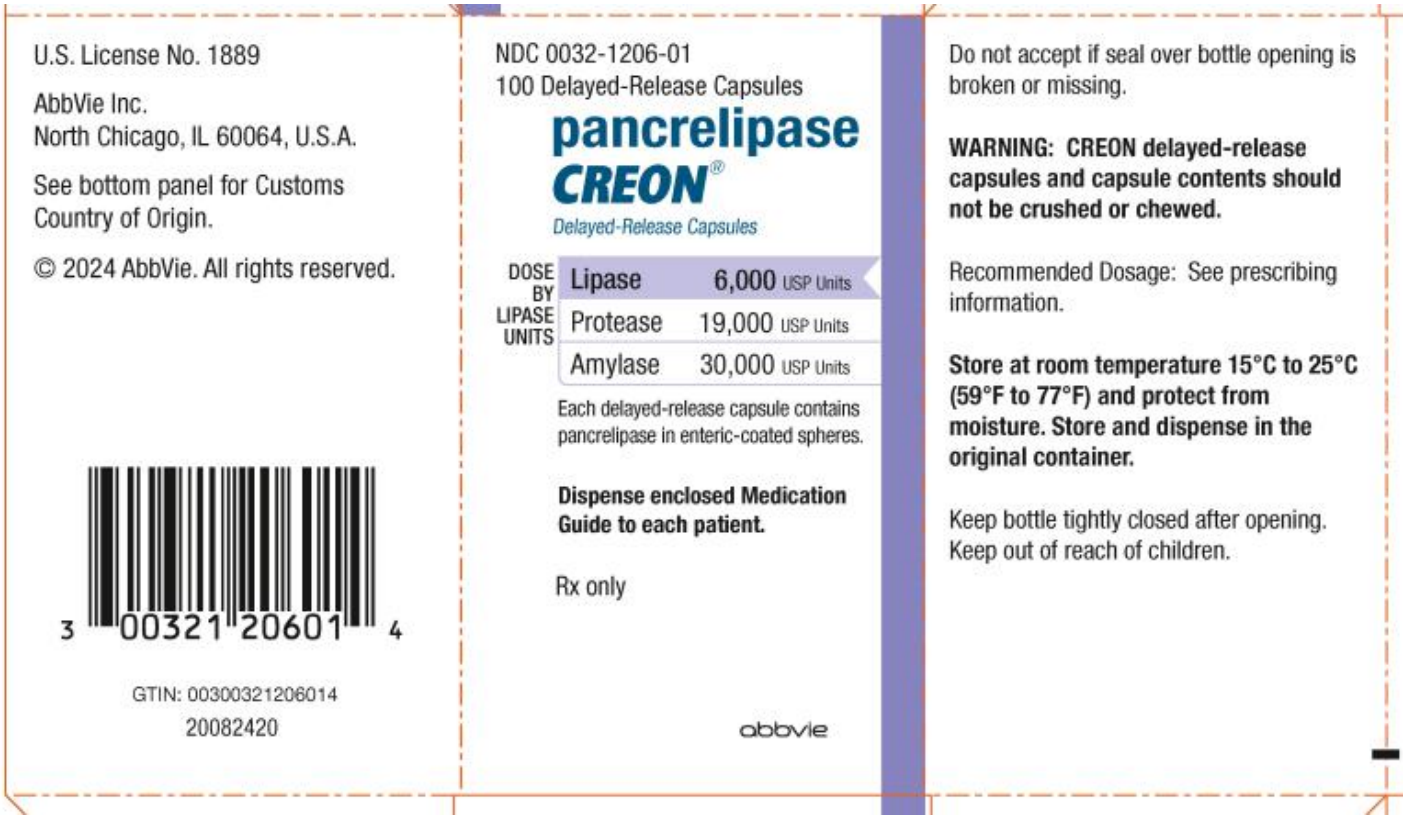

NDC 0032-0047-70
100 Delayed-Release Capsules
Rx only
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 12,000 USP Units
Protease 38,000 USP Units
Amylase 60,000 USP Units
Each delayed-release capsule contains
pancrelipase in enteric-coasted spheres.
**Dispense enclosed Medication Guide to each patient.**



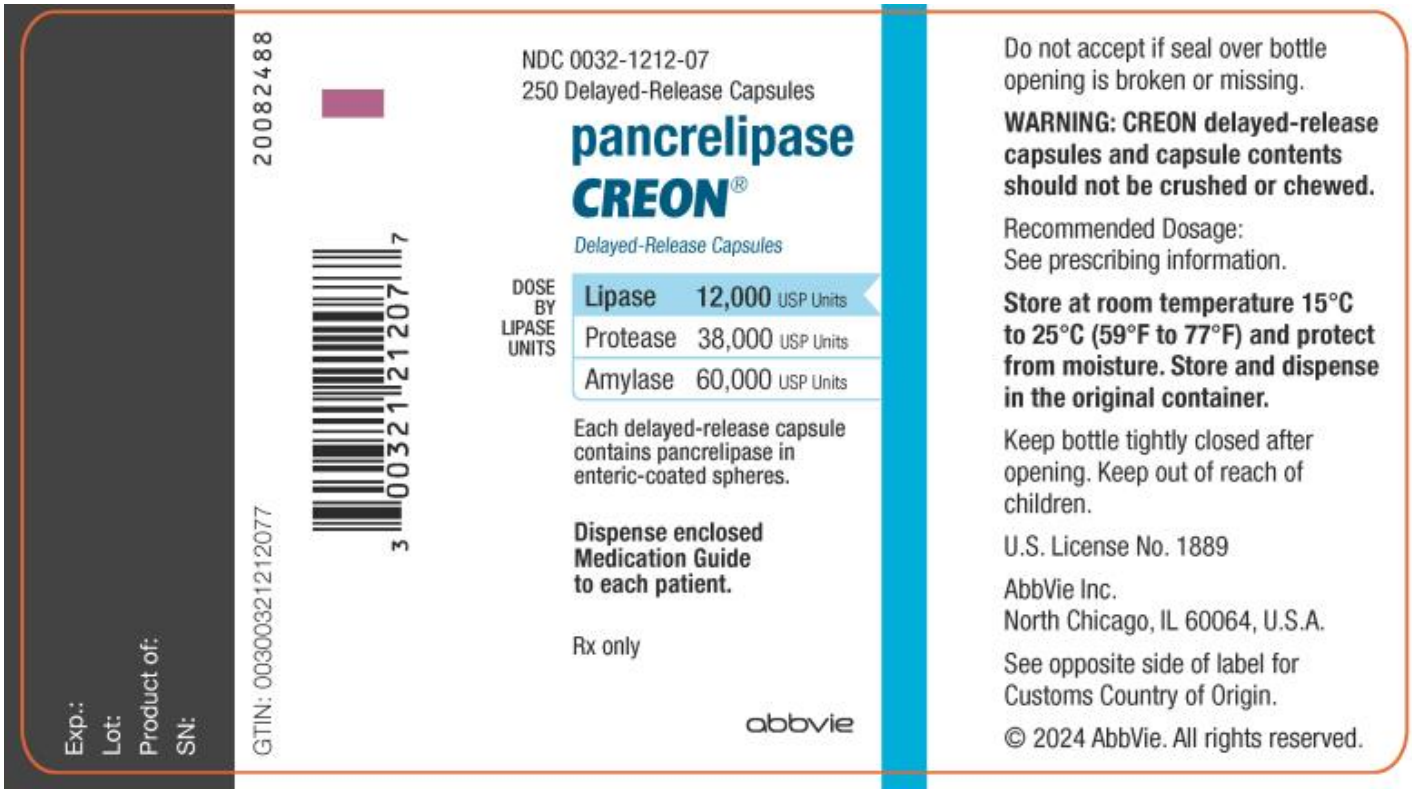

NDC 0032-1203-70
70 Delayed-Release Capsules
**Pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 3,000 USP Units
Protease 9,500 USP Units
Amylase 15,000 USP Units
Each delayed-release capsule contains pancrelipase in enteric-coated spheres.
**Dispense enclosed Medication Guide to each patient.**
Rx only
abbvie



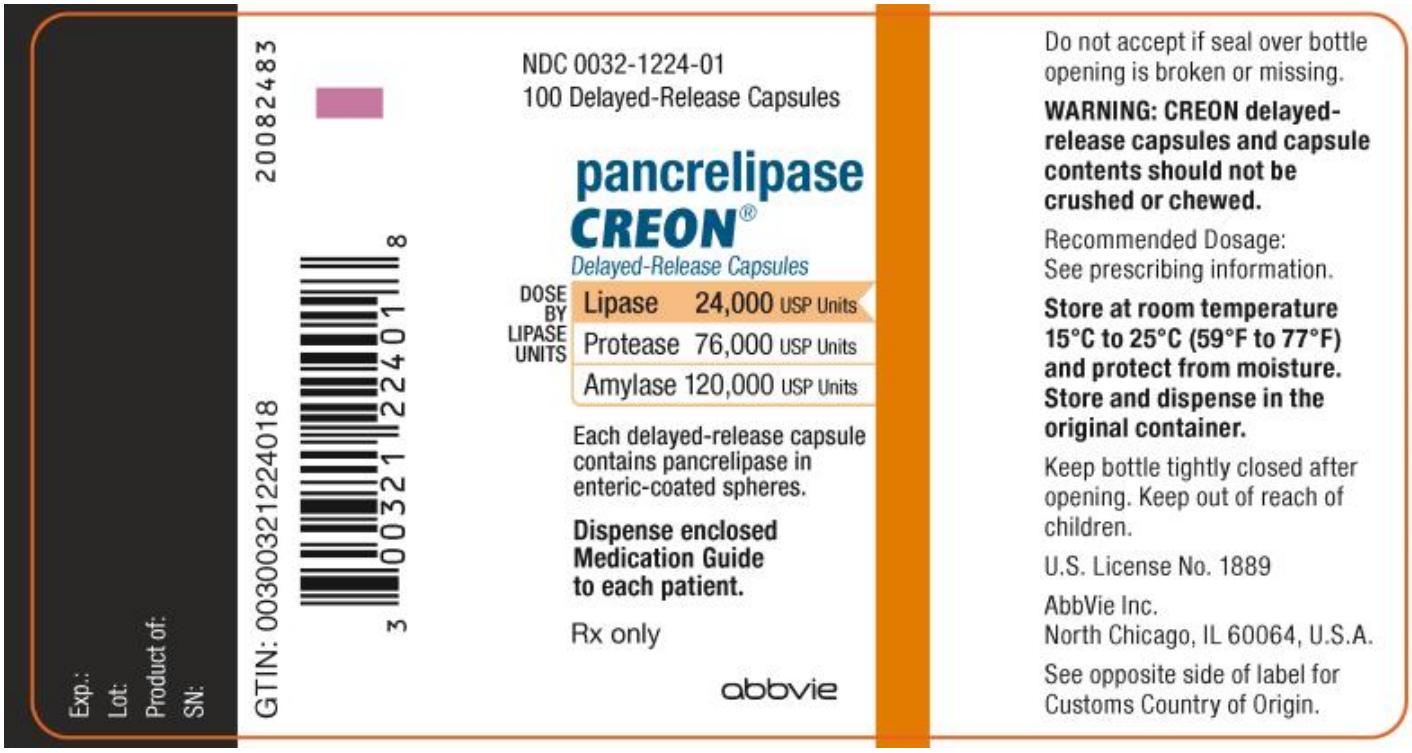

NDC 0032-1206-01
100 Delayed-Release Capsules
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 6,000 USP Units
Protease 19,000 USP Units
Amylase 30,000 USP Units
Each delayed-release capsule contains pancrelipase in enteric-coated spheres.
**Dispense enclosed Medication Guide to each patient.**
Rx only
abbvie



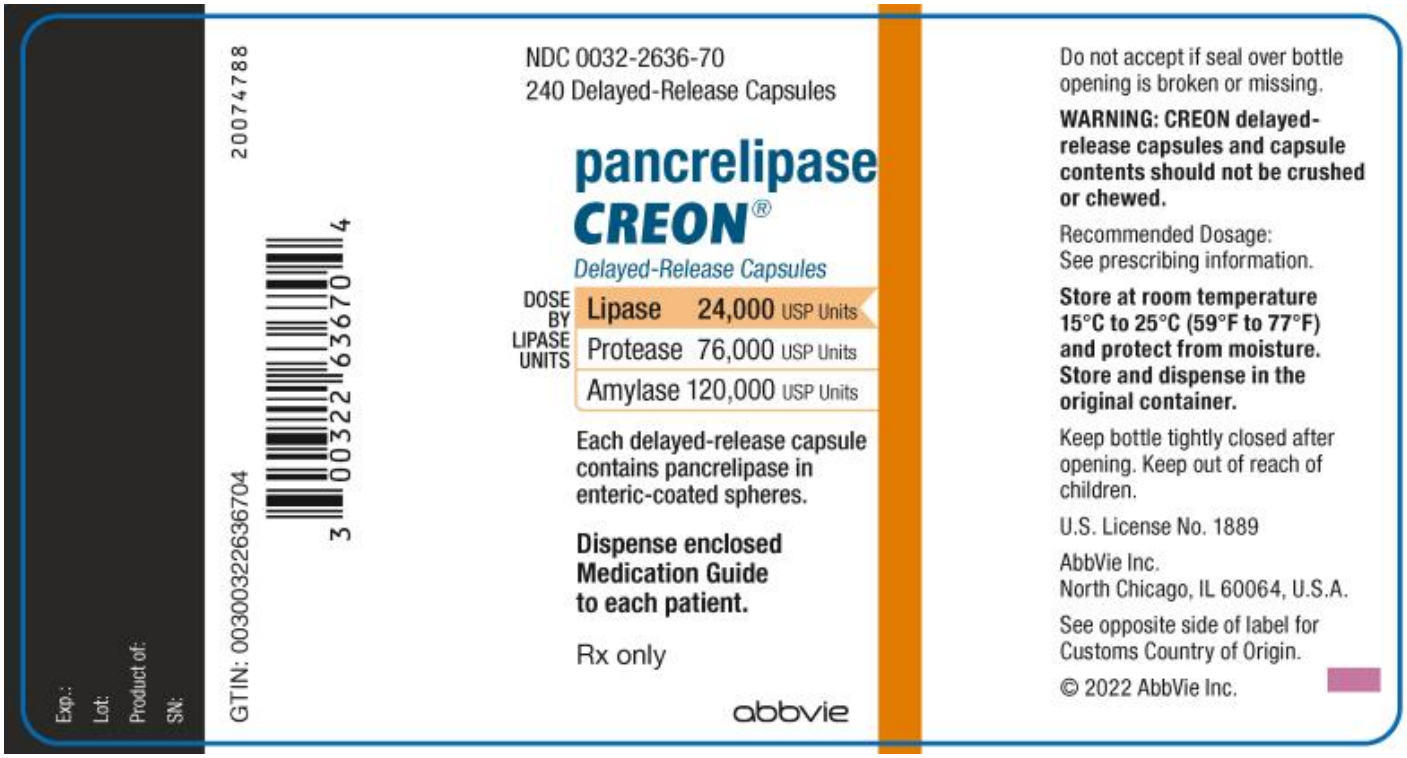

NDC 0032-1212-07
250 Delayed-Release Capsules
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 12,000 USP Units
Protease 38,000 USP Units
Amylase 60,000 USP Units
Each delayed-release capsule contains pancrelipase in enteric-coated spheres.
**Dispense enclosed Medication Guide to each patient.**
Rx only
abbvie



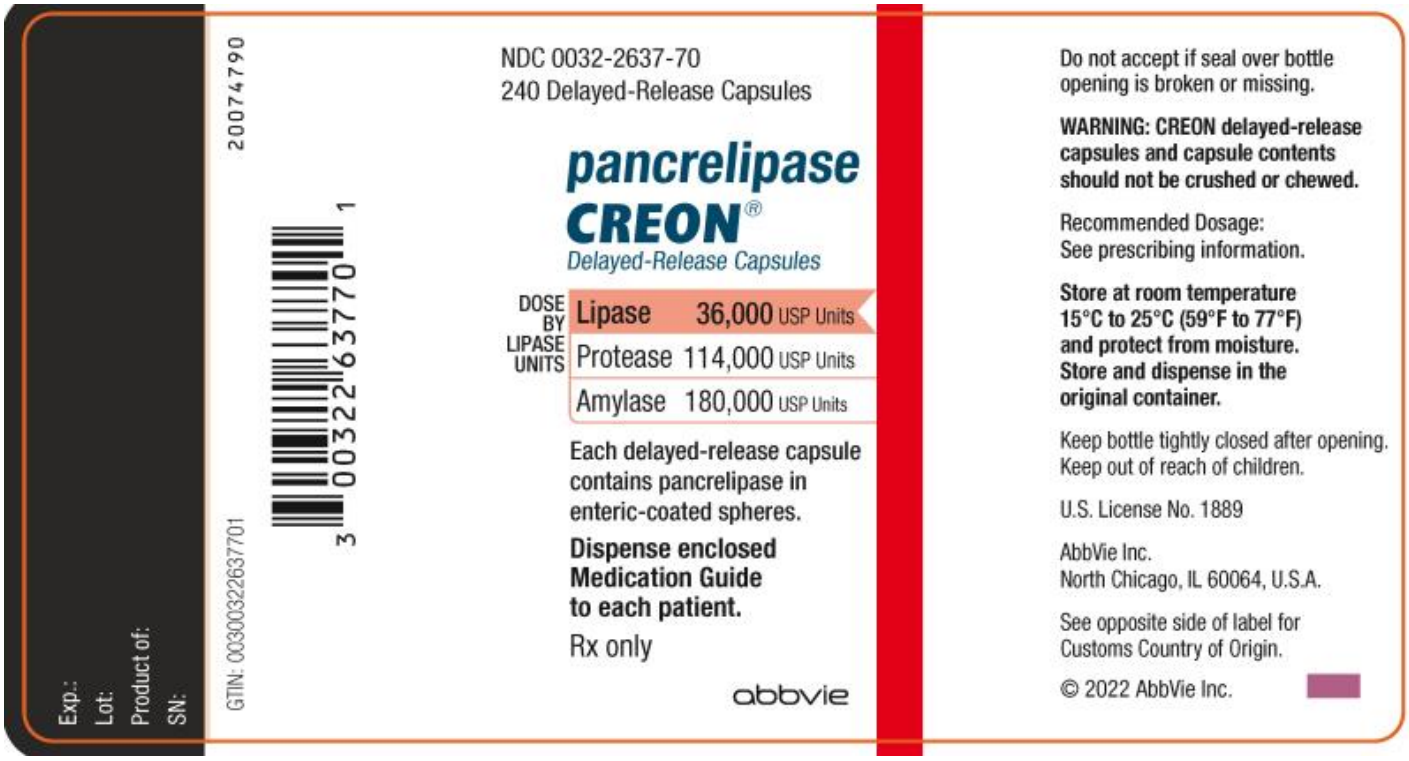

NDC 0032-1224-01
100 Delayed-Release Capsules
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 24,000 USP Units
Protease 76,000 USP Units
Amylase 120,000 USP Units
Each delayed-release capsule contains pancrelipase in enteric-coated spheres.
**Dispense enclosed Medication Guide to each patient.**
Rx only
abbvie



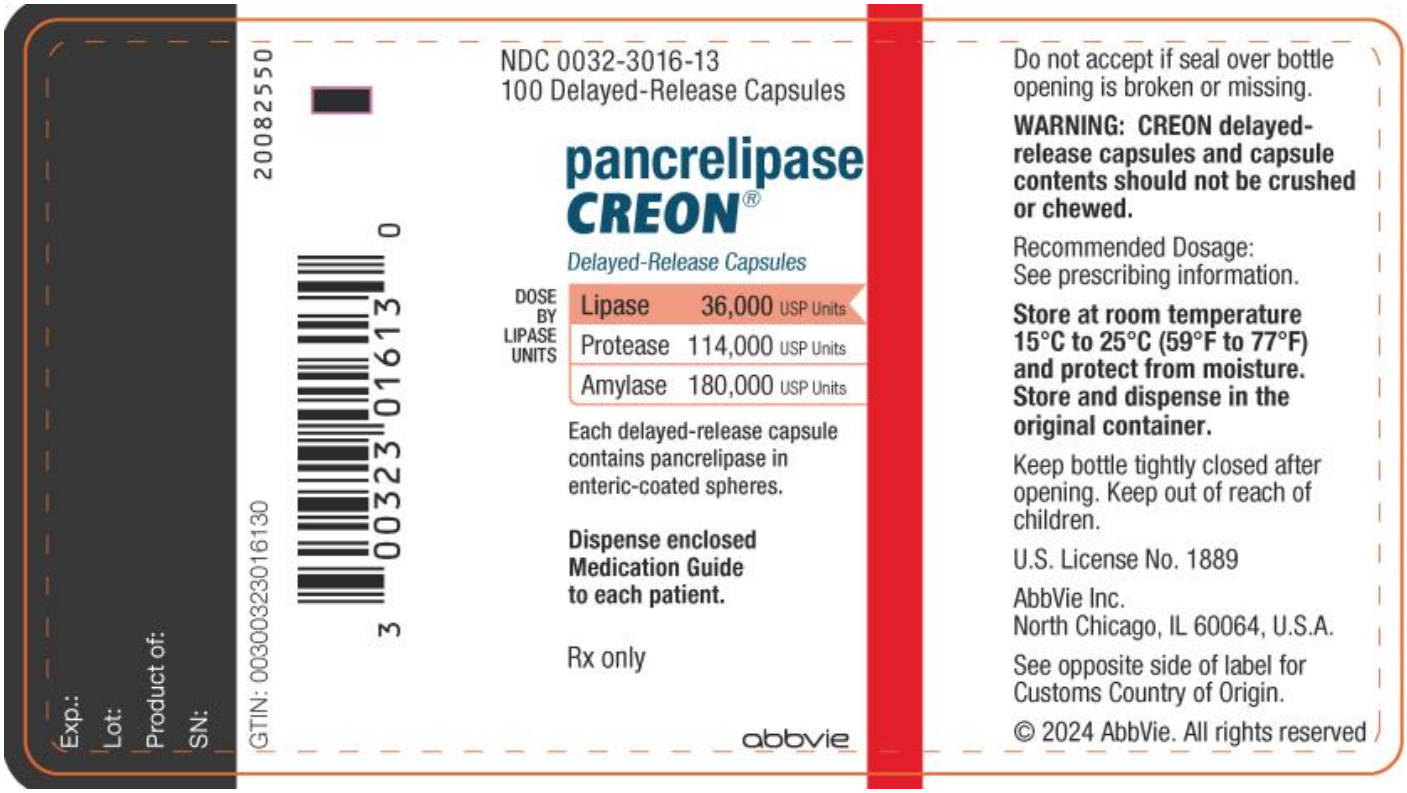

NDC 0032-2636-70
240 Delayed-Release Capsules
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 24,000 USP Units
Protease 76,000 USP Units
Amylase 120,000 USP Unites
Each delayed-release capsule contains
pancrelipase in enteric-coasted spheres.
**Dispense enclosed Medication Guide to each patient.**
Rx only
Abbvie




NDC 0032-2637-70
240 Delayed-Release Capsules
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
DOSE BY LIPASE UNITS:
Lipase 36,000 USP Units
Protease 114,000 USP Units
Amylase 180,000 USP Unites
Each delayed-release capsule contains pancrelipase in enteric-coasted spheres.
**Dispense enclosed Medication Guide to each patient.**
Rx only
Abbvie




NDC 0032-3016-13
100 Delayed-Release Capsules
**pancrelipase**
**CREON®**
*Delayed-Release Capsules*
CREON® (pancrelipase)
Delayed-Release Capsules
DOSE BY LIPASE UNITS:
Lipase 36,000 USP Units
Protease 114,000 USP Units
Amylase 180,000 USP Units
Each delayed-release capsule contains pancrelipase in enteric-coated spheres.
**Dispense enclosed Medication Guide to each patient.**
Rx only
abbvie




# CREON

pancrelipase capsule, delayed release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-1203 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 15000 [USP'U] |
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 3000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 9500 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| | |
|---|---|
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white (White opaque body and white opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | CREON;1203 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-1203-70 | 1 in 1 CARTON | 04/30/2009 | |
| **1** | | 70 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:0032-1203-64 | 1 in 1 CARTON | 04/30/2009 | |
| **2** | | 70 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 04/30/2009 | |

# CREON

pancrelipase capsule, delayed release pellets

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-1206 |
| **Route of Administration** | ORAL | | |

**Active Ingredient/Active Moiety**

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 30000 [USP'U] |
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 6000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 19000 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue (Blue opaque body) , orange (Orange opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | CREON;1206 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-1206-07 | 250 in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2009 | |
| **2** | NDC:0032-1206-01 | 1 in 1 CARTON | 04/30/2009 | |
| **2** | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:0032-1206-56 | 1 in 1 CARTON | 04/30/2009 | |
| **3** | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 04/30/2009 | |

# CREON

pancrelipase capsule, delayed release pellets

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-1212 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 60000 [USP'U] |
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 12000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 38000 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | brown (Colorless transparent body and brown opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 18mm |
| **Flavor** | | **Imprint Code** | CREON;1212 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-1212-07 | 250 in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2009 | |
| **2** | NDC:0032-1212-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2009 | |
| **3** | NDC:0032-1212-46 | 1 in 1 CARTON | 04/30/2009 | 03/31/2014 |

| | | | | |
|---|---|---|---|---|
| **3** | | 12 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **4** | NDC:0032-1212-13 | 1 in 1 CARTON | 11/20/2018 | |
| **4** | | 100 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 04/30/2009 | |

# CREON

pancrelipase capsule, delayed release pellets

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-1224 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 24000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 76000 [USP'U] |
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 120000 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | orange (Colorless transparent body and orange opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 22mm |
| **Flavor** | | **Imprint Code** | CREON;1224 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-1224-07 | 250 in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2009 | |
| **2** | NDC:0032-1224-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 04/30/2009 | |
| **3** | NDC:0032-1224-46 | 1 in 1 CARTON | 04/30/2009 | |
| **3** | | 12 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 04/30/2009 | |

# CREON

pancrelipase capsule, delayed release pellets

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-3016 |
| **Route of Administration** | ORAL | | |

**Active Ingredient/Active Moiety**

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 36000 [USP'U] |
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 180000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 114000 [USP'U] |

**Inactive Ingredients**

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |

| | |
|---|---|
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue (Colorless transparent body and blue opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 25mm |
| **Flavor** | | **Imprint Code** | CREON;1236 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-3016-28 | 250 in 1 BOTTLE; Type 0: Not a Combination Product | 03/14/2013 | |
| **2** | NDC:0032-3016-13 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 03/14/2013 | |
| **3** | NDC:0032-3016-50 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 03/14/2013 | 12/08/2017 |
| **4** | NDC:0032-3016-12 | 1 in 1 CARTON | 03/14/2013 | |
| **4** | | 12 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 03/14/2013 | |

# CREON

pancrelipase capsule, delayed release

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-0045 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 15000 [USP'U] |
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 3000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 9500 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white (White opaque body and white opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | CREON;1203 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-0045-70 | 70 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |
| **2** | NDC:0032-0045-30 | 70 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 10/12/2023 | |

# CREON

pancrelipase capsule, delayed release pellets

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-0046 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 30000 [USP'U] |
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 6000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 19000 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue (Blue opaque body) , orange (Orange opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | CREON;1206 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-0046-30 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |
| **2** | NDC:0032-0046-70 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 10/12/2023 | |

# CREON

pancrelipase capsule, delayed release pellets

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-0047 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 60000 [USP'U] |
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 12000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 38000 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FERROSOFERRIC OXIDE** (UNII: XM0M87F357) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | brown (Colorless transparent body and brown opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 18mm |
| **Flavor** | | **Imprint Code** | CREON;1212 |

| Contains | |
|---|---|

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:0032-0047-30 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |
| 2 | NDC:0032-0047-70 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 10/12/2023 | |

# CREON

pancrelipase capsule, delayed release pellets

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-2636 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 24000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 76000 [USP'U] |
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 120000 [USP'U] |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |

| | |
|---|---|
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange (Colorless transparent body and orange opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 22mm |
| **Flavor** | | **Imprint Code** | CREON;1224 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-2636-70 | 240 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |
| **2** | NDC:0032-2636-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |
| **3** | NDC:0032-2636-30 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 10/12/2023 | |

# CREON

pancrelipase capsule, delayed release pellets

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0032-2637 |
| **Route of Administration** | ORAL | | |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PANCRELIPASE LIPASE** (UNII: 8MYC33932O) (PANCRELIPASE LIPASE - UNII:8MYC33932O) | PANCRELIPASE LIPASE | 36000 [USP'U] |
| **PANCRELIPASE AMYLASE** (UNII: YOJ58O116E) (PANCRELIPASE AMYLASE - UNII:YOJ58O116E) | PANCRELIPASE AMYLASE | 180000 [USP'U] |
| **PANCRELIPASE PROTEASE** (UNII: 3560D81V50) (PANCRELIPASE PROTEASE - UNII:3560D81V50) | PANCRELIPASE PROTEASE | 114000 [USP'U] |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)** (UNII: G4U024CQK6) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **CARRAGEENAN** (UNII: 5C69YCD2YJ) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue (Colorless transparent body and blue opaque cap) | **Score** | no score |
| **Shape** | CAPSULE (OVAL) | **Size** | 25mm |
| **Flavor** | | **Imprint Code** | CREON;1236 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0032-2637-70 | 240 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |
| **2** | NDC:0032-2637-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 10/12/2023 | |
| **3** | NDC:0032-2637-30 | 1 in 1 CARTON | 10/12/2023 | |
| **3** | | 24 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA020725 | 10/12/2023 | |

## Labeler - AbbVie Inc. (078458370)

Revised: 2/2024 AbbVie Inc.