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REPRINT

ULTRASE®/ULTRASE® MT (pancrelipase) CAPSULES

Pancreatic Enzyme Supplementation

In July 2007, **Axcan Pharma™ (Birmingham, AL)**, submitted a New Drug Application (NDA) for its pancreatic enzyme replacement therapy drug **ULTRASE® MT (pancrelipase) Capsules** and is working on the application for **ULTRASE® (pancrelipase) Capsules.** This NDA was submitted in response to new guidelines issued by the FDA (outlined in April 2004 and finalized in April 2006). In these guidelines the FDA declared that all exocrine pancreatic insufficiency drug products were to be considered new products and, consequently, manufacturers who wanted to continue marketing such products were to submit an NDA.[1] These applications were required to include studies proving the safety and efficacy of such products. The FDA's requirement for NDAs was based upon *in vitro* and *in vivo* studies which prompted concerns about significant differences in bioavailability among pancreatic enzyme products and resultant problems with over and under-dosing.[1,2] The FDA attributed the differences in bioavailability to the broad range of enzyme activity in the products, the variety of dosage forms marketed, and differences of the enteric coatings.[3]

"This is a unique class of drugs that predates the Federal Food, Drug and Cosmetic Act which has been grandfathered through the system," notes Robert Kuhn, Pharm. D., University of Kentucky College of Pharmacy (Lexington, KY). "With the FDA mandating the NDA process and the required clinical trials, these products will now all have to meet the same standards of safety and efficacy." Dr. Kuhn continues, "As the new preparations are licensed, we should see a decrease in product variability because the number of the so-called "generic" preparations will drop dramatically. With the companies that have done clinical work, like Axcan, I think you will be assured, at least from a pharmacist's perspective, that you will have reproducibility and little variability in the product."

Pancreatic enzyme products such as **ULTRASE® and ULTRASE® MT** are indicated as replacement therapy to treat conditions for patients with partial or complete exocrine pancreatic insufficiency caused by Cystic Fibrosis (CF), chronic pancreatitis due to alcohol use or other causes, surgery, obstruction, other pancreatic disease and poor mixing.[4] In order for patients to receive an adequate dosage, they must rely upon the consistency of a known dose of a specific pancreatic enzyme. Optimal dosing for patients is usually based on a series of trials and evaluations. Variations between capsules or batches of similar products or brands, however, can lead to inconsistent absorption of essential nutrients in persons with pancreatic insufficiency. According to Dr. Kuhn, despite a demonstrated lack of bioequivalence, substitutions of preparations are often made without physician or patient consent or knowledge. "There are distinct differences between these enzyme preparations, not only in the amount of enzyme quantitatively, but also qualitatively, such as the resistance of the enteric coating. As a pharmacist, I do not think these drugs are therapeutically interchangeable. Having worked with CF doctors for the past 25 years, it has become abundantly clear that substituting one preparation for another can affect clinical outcomes. If a patient who is taking one product, such as **ULTRASE® MT**, and he or she is switched over to another preparation, the patient may experience an increase of symptoms, including steatorrhea, decreased fat absorption, or increased GI symptoms, even though the labeled amounts are exactly the same. This

should emphasize the need to be consistent with the products and their delivery."

Dr. Kuhn and his colleagues investigated the *in vitro* variability of key elements in a group of currently available pancreatic enzyme formulations. They evaluated three "branded" preparations (Creon 20 Minimicrospheres, Pancrease MT 20, Ultrase MT 20), and three "generic" formulations (Pangestyme CN-20, Pancrelipase 20,000 URL, and Lipram CR 20) for physical parameters of the capsules, actual versus labeled enzyme activity, resistance of the enteric coating to simulated gastric acid, and kinetics of simulated duodenal lipase release.[3] Their study confirmed the existence of variability in branded-to-generic, product-to-product, and batch-to-batch among the pancreatic enzyme formulations with pharmaceutically equivalent labels.[3] Dr. Kuhn maintains that in his mind, "Less variability probably means better preparations because they are going to be more predictable. This is significant for patients because optimal therapeutic dosing of pancreatic enzymes will effect an improvement of their symptoms and an improvement in the absorption of fat-soluble vitamins, leading to an overall improvement in their well-being."

Kraisinger, et al., also point out that pancreatic enzyme preparations are not necessarily the functional equivalent of each other, noting "the clinical efficacy of pancreatic enzymes in patients with CF is a function of the amount of biologically active enzyme that reaches the small intestine. This is a function of the content of the product, acid stability and the pH at which the coating dissolves and releases active enzyme."[5]

Axcan Pharma's NDA is based on a clinical study program that included Phase III, multi-center, double-blinded, placebo-controlled cross-over trials. In the initial two Phase III studies previously disclosed, patients with pancreatic insufficiency associated with CF received ULTRASE® MT12, ULTRASE® MT20, or placebo. The results of this study showed excellent effects on fat absorption with minimal adverse events. Baseline fat absorption levels without enzyme supplementation were 46.7% and 58.7% respectively in the ULTRASE® MT12 and ULTRASE® MT20 study groups. Mean fat absorption increased to 79.4% and 87.3% respectively for the ULTRASE® MT12 and ULTRASE® MT20 study groups.[6]

Ultrase® and Ultrase® MT (pancrelipase) Capsules are orally administered capsules containing enteric-coated microspheres or minitablets of porcine pancreatic enzyme concentrate, predominantly pancreatic lipase, amylase, and protease. ULTRASE® and ULTRASE® MT are indicated for patients with partial or complete exocrine pancreatic insufficiency caused by: cystic fibrosis, chronic pancreatitis due to alcohol use or other causes, surgery, obstruction, other pancreatic disease and poor mixing. Pancrelipase capsules are effective in controlling steatorrhea caused by exocrine pancreatic insufficiency.[4]

Pancrelipase capsules are contraindicated in patients known to be hypersensitive to pork protein. Pancrelipase capsules are contraindicated in patients with acute pancreatitis or with acute exacerbations of chronic pancreatic diseases. The most frequently reported adverse reactions to products containing pancrelipase are gastrointestinal in nature. Less frequently, allergic-type reactions have also been observed. Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricosuria and hyperuricemia when the preparations given were pancrelipase in powdered or capsule form. [4]

Colonic strictures have been reported in cystic fibrosis patients treated with both high- and lower-strength enzyme supplements. A causal relationship has not been established. The possibility of bowel stricture should be considered if symptoms suggestive of gastrointestinal obstruction occur. Since impaired fluid secretion may be a factor in the development of intestinal obstruction, care should be taken to maintain adequate hydration, particularly in warm weather. [4]

For more information about **ULTRASE® and ULTRASE® MT** or other Axcan Pharma™ products, please call (800)-950-8085, visit the company's web site at www.axcan.com, or visit a company representative at ACG, Booth # 1813.

References:

1. FDA, Exocrine pancreatic insufficiency drug products; draft guidance for submitting new drug applications; Notices, 2004; Vol. 69, No. 82; 23410-23414.
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ULTRASE®

('ul-trās)
(pancrelipase) Capsules
Enteric-Coated Microspheres

Prescribing Information

DESCRIPTION:
ULTRASE® (pancrelipase) Capsules are orally administered and contain 250 mg of enteric-coated microspheres of porcine pancreatic enzyme concentrate, predominantly pancreatic lipase, amylase, and protease.

Each ULTRASE® Capsule contains:

Lipase	4,500 U.S.P. Units
Amylase	20,000 U.S.P Units
Protease	25,000 U.S.P. Units

Inactive ingredients: povidone, talc, sugar, methacrylic acid copolymer (Type C), triethyl citrate, simethicone emulsion.

CLINICAL PHARMACOLOGY:
ULTRASE® (pancrelipase) Capsules are designed to prevent inactivation by gastric acid thereby resulting in the delivery of high levels of biologically active enzymes into the duodenum. The enzymes catalyze the hydrolysis of fats into glycerol and fatty acids, starch into dextrins and sugars, and protein into proteoses and derived substances.

INDICATIONS AND USAGE:
ULTRASE® (pancrelipase) Capsules are indicated for patients with partial or complete exocrine pancreatic insufficiency caused by:
- Cystic fibrosis (CF)
- Chronic pancreatitis due to alcohol use or other causes
- Surgery (pancreatico-duodenectomy or Whipple's procedure, with or without Wirsung duct injection,total pancreatectomy)
- Obstruction (pancreatic and biliary duct lithiasis, pancreatic and duodenal neoplasms, ductal stenosis)
- Other pancreatic disease (hereditary, post traumatic and allograft pancreatitis, hemochromatosis, Shwachman's Syndrome, lipomatosis, hyperparathyroidism)
- Poor mixing (Billroth II gastrectomy, other types of gastric bypass surgery, gastrinoma)

Pancrelipase capsules are effective in controlling steatorrhea.[1-9]

CONTRAINDICATIONS:
Pancrelipase capsules are contraindicated in patients known to be hypersensitive to pork protein. Pancrelipase capsules are contraindicated in patients with acute pancreatitis or with acute exacerbations of chronic pancreatic diseases.

WARNINGS:
Should hypersensitivity occur, discontinue medication and treat symptomatically.

PRECAUTIONS:
General
TO PROTECT ENTERIC COATING, MICROSPHERES MUST NOT BE CRUSHED OR CHEWED. Where swallowing of capsules is difficult, they may be opened and the microspheres added to a small quantity of a soft food (e.g., applesauce, gelatin, etc.) that does not require chewing, and swallowed immediately. Contact of the microsphere with foods having a pH greater than 5.5 can dissolve the protective enteric shell.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals have not been performed to evaluate carcinogenic potential. Methacrylic acid, a minor component of the methacrylic acid copolymer enteric-coating contained in ULTRASE® (pancrelipase) Capsules, has been reported to act as a teratogen in rat embryo cultures. However, the copolymer enteric-coating of ULTRASE® (pancrelipase) Capsules was not mutagenic by the Ames test, and it did not produce chromosome damage in a test for unscheduled DNA synthesis in rat hepatocytes.

Pregnancy: Category C.
Animal reproduction studies have not been conducted with ULTRASE® (pancrelipase) Capsules. It is not known whether ULTRASE® (pancrelipase) Capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ULTRASE® (pancrelipase) Capsules should be given to a pregnant woman only if the potential benefit outweighs the potential risk to the fetus.

Nursing Mothers
It is not known whether ULTRASE® (pancrelipase) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ULTRASE® (pancrelipase) Capsules are administered to a nursing mother.

ADVERSE REACTIONS:
The most frequently reported adverse reactions to products containing pancrelipase are gastrointestinal in nature. Less frequently, allergic-type reactions have also been observed. Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricosuria and hyperuricemia when the preparations given were pancrelipase in powdered or capsule form, or pancreatin in tablet form.

Colonic strictures have been reported in cystic fibrosis patients treated with both high- and lower-strength enzyme supplements.[10] A causal relationship has not been established. The possibility of bowel stricture should be considered if symptoms suggestive of gastrointestinal obstruction occur. Since impaired fluid secretion may be a factor in the development of intestinal obstruction, care should be taken to maintain adequate hydration, particularly in warm weather.[11]

"Fibrosing colonopathy" is a term used to describe a condition seen in patients with CF who have taken high amounts of pancreatic enzyme supplements (>6,000 lipase U/kg/meal). At its most advanced, this condition leads to colonic strictures.

1. In whom should one consider the diagnosis of fibrosing colonopathy?
a. Patients with cystic fibrosis who have evidence of partial or complete obstruction, bloody diarrhea or chylous ascites.
b. Patients who have two of the following three symptoms:
   - abdominal pain
   - ongoing diarrhea
   - poor weight gain

   ESPECIALLY if they have:
   - taken >6,000 lipase U/kg/meal
   - age less than twelve years
   - history of meconium ileus
   - prior intestinal surgery
   - history of recurrent DIOS
   - "inflammatory bowel disease"[12]

DOSAGE AND ADMINISTRATION:
The enzymatic activity of ULTRASE® (pancrelipase) Capsules is expressed in U.S.P. units.
The smallest effective dose should be used. Dosage should be adjusted according to the severity of the exocrine pancreatic insufficiency. Begin therapy with one or two capsules with meals or snacks and adjust dosage according to symptoms. The number of capsules or capsule strength given with meals and/or snacks should be estimated by assessing which dose minimizes steatorrhea and maintains good nutritional status. Dosages should be adjusted according to the response of the patient. Where swallowing of capsules is difficult, they may be opened and the microspheres added to a small quantity of a soft food (e.g., applesauce, gelatin, etc.) that does not require chewing, and swallowed immediately. It is recommended that the total dose of pancrelipase being ingested for a meal or snack be dispersed equally (with fluids) before, during, and after the meal or snack.

SUGGESTIONS FOR THE USE OF PANCREATIC ENZYMES IN CYSTIC FIBROSIS[12]
1. Patients should be receiving optimal diet for age and clinical status, recognizing that those with failure to thrive or malnutrition require additional calories and other nutrients for catch-up growth.
2. Nutrition assessment should be a part of routine clinical evaluations.
3. Initial dosing of pancreatic enzyme supplements should begin with 500 lipase U/kg/meal using enteric-coated microsphere products.
4. Patients should be reassessed 2-4 weeks after initiation of therapy. The following items should be assessed:
   - Clinical status, e.g., abdominal symptoms and exam;
   - Nutritional intake and growth (height, weight, head circumference);
   - Character of stools - greasy, oily (for information, not for decision making);
   - Quantitative 72-hour fecal fat when indicated but not less than annually (perform on a normal diet for age);
   - Fat soluble vitamin measures.
5. Corollaries to dosing suggestions:
   a. Dose may be altered in a stepwise fashion according to the response of the patient (see 4. above).
   b. Dose approaching 2,000 lipase U/kg/meal would indicate the need for further investigation (see below). Patients presently on higher doses should be reevaluated; either immediately decrease the dose or titrate down to a lower dose range at, or below, 2,000 lipase U/kg/meal. Doses >6,000 lipase U/kg/meal have been associated with colonic strictures.
   c. Pancreatic supplements mixed with applesauce or other acidic food substances should be administered immediately, not stored.
   d. Enteric-coated microspheres should not be crushed.
   e. Enzyme doses (as lipase U/kg/meal) tend to decrease with advancing age.
   f. Patients should accept only product brands prescribed by their physician.
   g. Adjustment of dosage is the responsibility of the physician. Patients should be advised not to adjust doses without consulting their physician. Changes in product or dosage may require an adjustment period.
   h. Complaints transmitted by phone should be investigated thoroughly before dose is adjusted. If indicated, this investigation should include 72-hour fecal fat testing.
   i. Pancreatic supplements should be stored in a cool, dry place and checked regularly for expiration date.

HOW SUPPLIED:
ULTRASE® (pancrelipase) Capsules
Gelatin capsules (opaque white and opaque white), imprinted "ULTRASE". Bottles of 100 (NDC 58914-045-10).

Store at controlled room temperature, between 15°C and 25°C (59°F and 77°F), in a dry place. Do not refrigerate.

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11. Lands L, Zinman R, et al. Pancreatic function testing in meconium disease in CF: two case reports. J Ped Gastroenterol and Nut. 1988;7:276-279.
12. Cystic Fibrosis Foundation Conference on Pancreatic Enzyme Supplementation in the Context of Fibrosing Colonopathy; Washington, D.C., March 23-24, 1995.

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AXCAN SCANDIPHARM INC.
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Birmingham, AL 35242 USA

www.axcan.com

AXCAN PHARMA™

2306020-01

ULTRASE® MT

('ul-trās)
(pancrelipase) Capsules
Enteric-Coated Minitablets

Prescribing Information

DESCRIPTION:
ULTRASE® MT (pancrelipase) Capsules are orally administered capsules containing enteric-coated minitablets of porcine pancreatic enzyme concentrate, predominantly pancreatic lipase, amylase, and protease.

Each ULTRASE® MT12 Capsule is orally administered and contains 223 mg of enteric-coated minitablets of porcine pancreatic concentrate containing:

Lipase	12,000 U.S.P. Units
Amylase	39,000 U.S.P. Units
Protease	39,000 U.S.P. Units

Each ULTRASE® MT18 Capsule is orally administered and contains 333 mg of enteric-coated minitablets of porcine pancreatic concentrate containing:

Lipase	18,000 U.S.P. Units
Amylase	58,500 U.S.P. Units
Protease	58,500 U.S.P. Units

Each ULTRASE® MT20 Capsule is orally administered and contains 371 mg of enteric-coated minitablets of porcine pancreatic concentrate containing:

Lipase	20,000 U.S.P. Units
Amylase	65,000 U.S.P. Units
Protease	65,000 U.S.P. Units

Inactive ingredients: gelatin, hydrogenated castor oil, silicon dioxide, magnesium stearate, croscarmellose sodium, microcrystalline cellulose, hydroxypropyl methylcellulose phthalate (HP 55) (as dry substance), talc, triethyl citrate, iron oxides and titanium dioxide.

CLINICAL PHARMACOLOGY:
ULTRASE® MT (pancrelipase) Capsules are designed to prevent inactivation by gastric acid thereby resulting in the delivery of high levels of biologically active enzymes into the duodenum. The enzymes catalyze the hydrolysis of fats into glycerol and fatty acids, starch into dextrins and sugars, and protein into proteoses and derived substances.

INDICATIONS AND USAGE:
ULTRASE® MT (pancrelipase) Capsules are indicated for patients with partial or complete exocrine pancreatic insufficiency caused by:
- Cystic fibrosis (CF)
- Chronic pancreatitis due to alcohol use or other causes
- Surgery (pancreatico-duodenectomy or Whipple's procedure, with or without Wirsung duct injection, total pancreatectomy)
- Obstruction (pancreatic and biliary duct lithiasis, pancreatic and duodenal neoplasms, ductal stenosis)
- Other pancreatic disease (hereditary, post traumatic and allograft pancreatitis, hemochromatosis, Shwachman's Syndrome, lipomatosis, hyperparathyroidism)
- Poor mixing (Billroth II gastrectomy, other types of gastric bypass surgery, gastrinoma)

Pancrelipase capsules are effective in controlling steatorrhea.[1-9]

CONTRAINDICATIONS:
Pancrelipase capsules are contraindicated in patients known to be hypersensitive to pork protein. Pancrelipase capsules are contraindicated in patients with acute pancreatitis or with acute exacerbations of chronic pancreatic diseases.

WARNINGS:
Should hypersensitivity occur, discontinue medication and treat symptomatically.

PRECAUTIONS:
General
TO PROTECT ENTERIC COATING, MINITABLETS MUST NOT BE CRUSHED OR CHEWED. Where swallowing of capsules is difficult, they may be opened and the minitablets added to a small quantity of a soft food (e.g., applesauce, gelatin, etc.) that does not require chewing, and swallowed immediately. Contact of the minitablet with foods having a pH greater than 5.5 can dissolve the protective enteric shell.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy: Category C.
Animal reproduction studies have not been conducted with ULTRASE® MT (pancrelipase) Capsules. It is not known whether ULTRASE® MT (pancrelipase) Capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ULTRASE® MT (pancrelipase) Capsules should be given to a pregnant woman only if the potential benefit outweighs the potential risk to the fetus.

Nursing Mothers
It is not known whether ULTRASE® MT (pancrelipase) is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ULTRASE® MT (pancrelipase) Capsules are administered to a nursing mother.

ADVERSE REACTIONS:
The most frequently reported adverse reactions to products containing pancrelipase are gastrointestinal in nature. Less frequently, allergic-type reactions have also been observed. Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricosuria and hyperuricemia when the preparations given were pancrelipase in powdered or capsule form, or pancreatin in tablet form.

In two clinical studies with ULTRASE® MT in 193 patients with cystic fibrosis, the adverse events described were all gastrointestinal in nature and may actually represent symptoms of the underlying disease, such as abdominal pain/cramps (5.7%), diarrhea (3.6%), and greasy stools and flatulence (1.5% each). In a postmarketing trial with another enteric-coated formulation, 160 adverse events occurred in the 15,711 patients (0.97%) evaluated.[10] The most frequent events reported were diarrhea, skin reaction, and abdominal discomfort (0.2% each).

Colonic strictures have been reported in cystic fibrosis patients treated with both high- and lower-strength enzyme supplements.[11] A causal relationship has not been established. The possibility of bowel stricture should be considered if symptoms suggestive of gastrointestinal obstruction occur. Since impaired fluid secretion may be a factor in the development of intestinal obstruction, care should be taken to maintain adequate hydration, particularly in warm weather.[12]

"Fibrosing colonopathy" is a term used to describe a condition seen in patients with CF who have taken high amounts of pancreatic enzyme supplements (>6,000 lipase U/kg/meal). At its most advanced, this condition leads to colonic strictures.

1. In whom should one consider the diagnosis of fibrosing colonopathy?
a. Patients with cystic fibrosis who have evidence of partial or complete obstruction, bloody diarrhea or chylous ascites.
b. Patients who have two of the following three symptoms:
   - abdominal pain
   - ongoing diarrhea
   - poor weight gain

   ESPECIALLY if they have:
   - taken >6,000 lipase U/kg/meal
   - age less than twelve years
   - history of meconium ileus
   - prior intestinal surgery
   - history of recurrent DIOS
   - "inflammatory bowel disease"[13]

DOSAGE AND ADMINISTRATION:
The enzymatic activity of ULTRASE® MT (pancrelipase) Capsules is expressed in U.S.P. units. The smallest effective dose should be used. Dosage should be adjusted according to the severity of the exocrine pancreatic insufficiency. Begin therapy with one or two capsules with meals or snacks and adjust dosage according to symptoms. The number of capsules or capsule strength given with meals and/or snacks should be estimated by assessing which dose minimizes steatorrhea and maintains good nutritional status. Dosages should be adjusted according to the response of the patient. Where swallowing of capsules is difficult, they may be opened and the minitablets added to a small quantity of a soft food (e.g., applesauce, gelatin, etc.) that does not require chewing, and swallowed immediately. It is recommended that the total dose of pancrelipase being ingested for a meal or snack be dispersed equally (with fluids) before, during, and after the meal or snack.

SUGGESTIONS FOR THE USE OF PANCREATIC ENZYMES IN CYSTIC FIBROSIS[13]
1. Patients should be receiving optimal diet for age and clinical status, recognizing that those with failure to thrive or malnutrition require additional calories and other nutrients for catch-up growth.
2. Nutrition assessment should be a part of routine clinical evaluations.
3. Initial dosing of pancreatic enzyme supplements should begin with 500 lipase U/kg/meal using enteric-coated minitablet products.
4. Patients should be reassessed 2-4 weeks after initiation of therapy. The following items should be assessed:
   - Clinical status, e.g., abdominal symptoms and exam;
   - Nutritional intake and growth (height, weight, head circumference);
   - Character of stools - greasy, oily (for information, not for decision making);
   - Quantitative 72-hour fecal fat when indicated but not less than annually (perform on a normal diet for age);
   - Fat soluble vitamin measures.
5. Corollaries to dosing suggestions:
   a. Dose may be altered in a stepwise fashion according to the response of the patient (see 4. above).
   b. Dose approaching 2,000 lipase U/kg/meal would indicate the need for further investigation (see below). Patients presently on higher doses should be reevaluated; either immediately decrease the dose or titrate down to a lower dose range at, or below, 2,000 lipase U/kg/meal. Doses >6,000 lipase U/kg/meal have been associated with colonic strictures.
   c. Pancreatic supplements mixed with applesauce or other acidic food substances should be administered immediately, not stored.
   d. Enteric-coated minitablets should not be crushed.
   e. Enzyme doses (as lipase U/kg/meal) tend to decrease with advancing age.
   f. Patients should accept only product brands prescribed by their physician.
   g. Adjustment of dosage is the responsibility of the physician. Patients should be advised not to adjust doses without consulting their physician. Changes in product or dosage may require an adjustment period.
   h. Complaints transmitted by phone should be investigated thoroughly before dose is adjusted. If indicated, this investigation should include 72-hour fecal fat testing.
   i. Pancreatic supplements should be stored in a cool, dry place and checked regularly for expiration date.

HOW SUPPLIED:
ULTRASE® MT12 (pancrelipase) Capsules
Gelatin capsules (white and yellow), imprinted "ULTRASE MT12". Bottles of 100 (NDC 58914-002-10).

ULTRASE® MT18 (pancrelipase) Capsules
Gelatin capsules (gray and white), imprinted "ULTRASE MT18". Bottles of 100 (NDC 58914-018-10).

ULTRASE® MT20 (pancrelipase) Capsules
Gelatin capsules (light gray and yellow), imprinted "ULTRASE MT20". Bottles of 100 (NDC 58914-004-10), and bottles of 500 (NDC 58914-004-50).

Store at controlled room temperature, between 15°C and 25°C (59°F and 77°F), in a dry place. Do not refrigerate.

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13. Cystic Fibrosis Foundation Conference on Pancreatic Enzyme Supplementation in the Context of Fibrosing Colonopathy; Washington, D.C., March 23-24, 1995.

Rx only

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