

VIOKASE[®]
(Pancrelipase, USP)
Tablets, Powder

Rx only

For product information please call 1-800-742-6706.

Description: VIOKASE[®] (pancrelipase, USP) is a pancreatic enzyme concentrate of porcine origin containing standardized lipase, protease, and amylase as well as other pancreatic enzymes. VIOKASE[®] is available in tablet and powder dosage form for oral administration.

The enzyme potencies of the tablets and powder are:

	VIOKASE[®] 8 Tablet	VIOKASE[®] 16 Tablet	VIOKASE[®] Powder Each 0.7 g (1/4 Teaspoonful)
Lipase, USP units	8,000	16,000	16,800
Protease, USP units	30,000	60,000	70,000
Amylase, USP units	30,000	60,000	70,000

Inactive Ingredients: VIOKASE[®] 8 and VIOKASE[®] 16 Tablets: Lactose, croscarmellose sodium, microcrystalline cellulose, silicon dioxide, stearic acid, talc. VIOKASE[®] Powder: Lactose, sodium chloride.

Clinical Pharmacology: The natural digestive enzymes in VIOKASE[®] hydrolyze fats into fatty acids and glycerol, split protein into amino acids, and convert carbohydrates to dextrans and short chain sugars.

Under conditions of the USP test method (in vitro) VIOKASE[®] has the following total digestive capacity:

	VIOKASE[®] 8 Tablet	VIOKASE[®] 16 Tablet	VIOKASE[®] Powder Each 0.7 g (1/4 Teaspoonful)
Dietary fat, grams	28	56	59
Dietary protein, grams	30	60	70
Dietary starch, grams	30	60	70

VIOKASE[®] 8 Tablets are 468 mg immediate release tablets and are not enteric-coated.

VIOKASE[®] 16 Tablets are 935 mg immediate release tablets and are not enteric-coated.

The digestive capacity of a pancreatic enzyme concentrate depends on the amount that passes through the stomach unchanged and is available at the site of action in the small intestine.

Indications: VIOKASE[®] (pancrelipase, USP) is indicated in the treatment of exocrine pancreatic insufficiency as associated with but not limited to cystic fibrosis, chronic pancreatitis, pancreatectomy, or obstruction of the pancreas ducts.

Contraindications: Should not be used in patients hypersensitive to pork protein.

Precautions: General: Individuals previously sensitized to trypsin, pancreatin or pancrelipase may have allergic manifestations.

Information for Patients: VIOKASE[®] should not be held in the mouth as the proteolytic action may cause irritation of the mucosa.

Avoid inhalation of the powder when administering VIOKASE[®].

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Carcinogenesis, Mutagenesis: Long-term studies in animals have not been performed to evaluate the carcinogenic potential.

Pregnancy Category C: Animal reproduction studies have not been conducted with VIOKASE[®]. It is also not known whether VIOKASE[®] can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. VIOKASE[®] should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when pancrelipase is administered to a nursing mother.

Adverse Effects: The dust or finely powdered pancreatic enzyme concentrate is irritating to the nasal mucosa and the respiratory tract. It has been documented that inhalation of the airborne powder can precipitate an asthma attack. The literature also contains several references to asthma due to inhalation in patients sensitized to pancreatic enzyme concentrates. Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricemia and hyperuricosuria. Overdosage of pancreatic enzyme concentrate may cause diarrhea or transient intestinal upset.

Overdose: Acute toxicity determinations in animals have not been possible since the maximum dose that could be given orally produced no toxic reaction. In chronic feeding tests rats developed swollen salivary glands. This is believed due to the proteolytic activity and the mucosal irritation caused by tissue digestion.

No acute toxic reactions have been reported.

Dosage and Administration: Powder: Dosage for patients with cystic fibrosis: 1/4 teaspoonful (0.7 g) with meals. Tablets: Dosage range for patients with cystic fibrosis or chronic pancreatitis is from 8,000 to 32,000 Lipase USP Units taken with meals, i.e., one to four VIOKASE® 8 tablets or one to two VIOKASE® 16 tablets with meals or as directed by a physician.

In patients with pancreatectomy or obstruction of pancreatic ducts: one to two VIOKASE® 8 tablets or one VIOKASE® 16 tablet taken at 2-hour intervals or as directed by a physician.

How Supplied: VIOKASE® 8 Tablets: Tan, round, compressed tablets engraved VIOKASE on one side and 9111 on the other side in bottles of 100 (NDC 58914-111-10) and 500 (NDC 58914-111-50).

VIOKASE® 16 Tablets: Tan, oval, biconvex tablets engraved V¹⁶ on one side and 9116 on the other side in bottles of 100 (NDC 58914-116-10).

Powder: Tan powder in bottles of 8 oz (227 g) (NDC 58914-115-08).

Store in tightly closed container in a dry place at a temperature not exceeding 25°C (77°F).

Dispense tablets and powder in tight container, preferably with a desiccant.

References:

1. Regan PT, Malagelada J-R, DiMugno EP, Gianzman SL, Go VLW. Comparative effects of antacids, cimetidine and enteric coating on the therapeutic response to oral enzymes in severe pancreatic insufficiency. *N Engl J Med* 1977;297:854-8.
2. Graham DY. Enzyme replacement therapy of exocrine pancreatic insufficiency in man. *N Eng J Med* 1977;296:1314-7.

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Manufactured in Canada for:
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