Viokase[®]-V

Tablet 425 mg Powder

WHOLE PANCREAS NOT AN EXTRACT NOT ENTERIC COATED

Each 425 mg tablet contains:

Lipase 9,000 USP units
Protease 57,000 USP units
Amylase 64,000 USP units
Each 2.8 grams (1 teaspoonful) of powder contains:
Lipase 71,400 USP units
Protease 388,000 USP units
Amylase 460,000 USP units

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: VIOKASE-V is activated whole raw pancreas; a pancreatic enzyme concentrate of porcine origin containing standardized amylase, protease and lipase activities plus esterases, peptidases, nucleases and elastase.

BACKGROUND INFORMATION: A review of the literature over the past 20 years, together with clinical experience, prompts the conclusion that pancreatitis is an important disease in the dog. Evidence of the disease was observed in approximately 3% of a series of dogs necropsied at the Angell Memorial Animal Hospital. Others have classified disease of the pancreas into 4 distinctive categories: acute necrotic pancreatitis; subacute or chronic pancreatitis; pancreatic fibrosis; and collapse or atrophy of the acinar pancreatic tissue. Only acute and chronic pancreatitis is readily recognized clinically.

Dogs that acquire acute pancreatitis usually recover, but are subject to exacerbations of the chronic inflammatory process that may persist. Complete healing of the acute lesion may not occur, and progressive destruction of the gland may take place over a period of months, even in the absence of clinical signs.

Chronic pancreatitis is characterized by acute exacerbations of pancreatic inflammation that occur after the remission of acute pancreatitis. Signs of the disease are similar to those of acute pancreatitis but are usually less severe.

Steatorrhea, diarrhea, weight loss and increased appetite characterize the digestive impairment caused by failure of pancreatic exocrine secretion. Secretion ceases when the acinar tissue is destroyed in the course of chronic pancreatitis. The sequela does not become evident until virtually total destruction of the acinar pancreas has occurred, because as little as 12 to 20 percent of the exocrine pancreas can secrete enough pancreatic juice to sustain digestion. Thus, digestive impairment is a relatively late event in the pathogenesis of chronic pancreatitis. Transient episodes of fetid diarrhea may occur at the time of an acute exacerbation, and may be caused by a temporary reduction of pancreatic exocrine secretion. However, food engorgement or the ingestion of fatty food often precipitates an exacerbation of chronic pancreatitis and the character of the food, rather than the absence of pancreatic enzymes, may cause the diarrhea.

The veterinarian should not be too concerned about whether the pancreatic lesion is acute or chronic. Their primary concern should be to recognize pancreatic inflammatory disease and begin treatment. The

differentiation of acute and chronic pancreatitis is then made on the basis of history, and is of importance in advancing a prognosis.

VIOKASE-V will replace pancreatic enzymes' secretions after total pancreatectomy.

INDICATIONS: As a digestive aid; replacement therapy where digestion of protein, carbohydrate and fat is inadequate due to exocrine pancreatic insufficiency.

PRECAUTIONS: Discontinue use in animals with symptoms of sensitivity.

TREATMENT IN ACUTE AND CHRONIC PANCREATITIS: The most

important aspect of the treatment of acute pancreatitis is initiation of vigorous therapy aimed at combating pain and shock, restoring blood volume, blood pressure and renal function, with reducing pancreatic secretions and combating secondary infection of necrotic tissue. Animals surviving an acute attack should be placed on a bland and easily digested diet (such as Prescription Diet[®], i/d) and supplemented with VIOKASE-V.

In chronic pancreatitis, replacement therapy must be given for the duration of the animal's life. Three daily feedings of a bland and easily digested diet containing sufficient quantities of good quality proteins and carbohydrates and low levels of fat are recommended (i.e., Prescription Diet, i/d). VIOKASE-V is given with each meal at a dosage level sufficient to keep the feces normal.

ADMINISTRATION AND DOSAGE: The VIOKASE-V tablets are administered before each meal. VIOKASE-V powder is added to moistened dog food (canned or dry). Thorough mixing is necessary to bring the enzymes into close contact with the food particles. Incubation at room temperature for 15–20 minutes before feeding appears to enhance the digestive process. Frequent feeding, at least 3 times daily is important.

USUAL DOSAGE: Dogs: 2–3 tablets or ¾–1 teaspoonful (2.8 g/teaspoonful) with each meal.

Cats: ½-1 tablet or ¼-¾ teaspoonful (2.8 g/teaspoonful) with each meal.

NOTE: No one regimen will be successful for every patient. The above dosage should be adjusted according to the severity of the pancreatic exocrine deficiency and weight of the animal. In cases of chronic insufficiency, the dosage should be increased until desired results are obtained.

Each tablet contains sufficient pancreatic enzymes to digest (in vitro):

33 g fat 57 g protein 64 g starch

Each 2.8 grams (1 teaspoonful) contains sufficient pancreatic enzymes to digest *(in vitro)*:

260 g fat 388 g protein 460 g starch

HOW SUPPLIED

VIOKASE-V Tablets—425 mg each in bottles of 100 and 500. VIOKASE-V Powder—Bottles of 4 ounce, 8 ounce and 12 ounce. NDC 0856-9301-63 — 100 tablets — bottle NDC 0856-9303-12 — 4 oz — bottle NDC 0856-9303-25 — 8 oz — bottle NDC 0856-9303-22 — 12 oz — bottle

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

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