ADVERSE REACTIONS:

The most common adverse reactions reported were poor food intake, vomiting, lethargy, decreased appetite, and weakness. Occasionally, more serious reactions, including collapse, dehydration, diarrhea, hypocalcemia, and seizures have been reported. In a US field study with 107 dogs, adrenal necrosis/rupture (two dogs) and hypoadrenocorticism (two dogs) were the most severe adverse reactions. Two dogs developed hypoadrenocorticism during the study. These two dogs had clinical signs consistent with hypoadrenocorticism (lethargy, anorexia, collapse) and post-ACTH cortisol levels ≤ 0.3 µg/dL. Both dogs responded to trilostane discontinuation and supportive care, and one dog required continued treatment for hypoadrenocorticism (glucocorticoids and mineralocorticoids) after the acute phase. In a UK field study with 75 dogs, the most common adverse reactions seen were vomiting, lethargy, diarrhea, restlessness, and ataxia. These adverse reactions included rectal, urinal, cough, persistent retch, vaginal discharge and swelling in a spared female, hypoadrenocorticism, electrolyte imbalance (elevated potassium with or without decreased sodium), collapse and coma, weakness, muscular incoordination, scratching, weight loss, and pain. One dog died of congestive heart failure and another died of pulmonary thromboembolism. These dogs were euthanized during the study. Two dogs had renal failure and another had worsening arrhythmia and vomiting.

In a US field study with 107 dogs, the following adverse reactions were seen: hypoadrenocorticism (e.g., syncope, tremor, weakness, vomiting, diarrhea, collapse, anorexia, weakness, and coma), hypopituitarism, hyperkalemia and hypocalcemia, hypoadrenocorticism (hypoglycemia and electrolyte imbalances), colitis, weakness, encephalopathy, and hypoadrenocorticism. Adverse reactions such as vomiting, diarrhea, persistent retch, weight loss, collapse, or any other unusual developments. If these clinical signs are observed, conduct an ACTH stimulation test and serum biochemical tests (with particular attention to electrolytes, and renal and hepatic function). For a cumulative list of adverse reactions for trilostane reported to the FDA see http://www.fda.gov/animalVeterinary/adverseEventsReportAdverseEvents.htm.

The following includes Adverse Events reported to CVM for products, such as VETORYL Capsules, that contain the active ingredient trilostane. All adverse reactions may be related to any brand name.

INFORMATION FOR DOG OWNERS:

Owners should be advised of the importance of periodic follow-up for all dogs during administration of VETORYL Capsules. VETORYL Capsules should be given with food to minimize gastrointestinal upset. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at: http://www.fda.gov/reportanimalae

CLINICAL PHARMACOLOGY:

Clinical pharmacology: Trilostane absorption is enhanced by administration with food. In healthy dogs, maximal plasma levels of VETORYL occur within 1.5 hours, returning to baseline by 12 hours, and declining to 10% of peak levels by 24 hours. There is no accumulation of trilostane or its metabolites over time.

EFFECTIVENESS: Eighty-three dogs with hypoadrenocorticism were enrolled in a multi-center US field study. Adiologically, 30 dogs with hypoadrenocorticism were enrolled in two UK field studies. Results from these studies demonstrated that treatment with VETORYL Capsules results in an absence of clinical signs consistent with hyperadrenocorticism (i.e., decreased food intake, decreased body weight, increased abdominal girth, reduced appetite, weight loss, and lethargy). Appropriate laboratory tests to establish hematological and serum biochemical baseline data prior to, and periodically during, administration of VETORYL Capsules should be considered. Owners should be advised to discontinue therapy immediately and contact their veterinarian if signs of potential drug toxicity occur. Appropriate laboratory tests should be performed (at initiation and re-examination, and periodically during therapy).

Some dogs will develop hair loss. Owners should be advised to continue therapy until the animal no longer exhibits clinical evidence of hyperadrenocorticism. If hair loss is severe, Owners should be advised to discontinue therapy and contact their veterinarian. Owners should be advised that hair loss may be permanent. Owners should be advised to continue therapy until the animal no longer exhibits clinical evidence of hyperadrenocorticism. If hair loss is severe, Owners should be advised to discontinue therapy and contact their veterinarian. Owners should be advised that hair loss may be permanent. Owners should be advised that hair loss may be permanent.

UNLABLES OR OBSERVE LABEL DIRECTIONS:

Adcircoronal suppressant for oral use in dogs only.

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

DESCRIPTION: VETORYL Capsules are available in 5 sizes (10, 30, 60, and 120 mg) for oral administration to dogs. Each VETORYL Capsule (17β-hydroxy-21-hydroxylated progesterone) contains 1 mg of trilostane (o,p'-DDD) as an active synthetic steroidal analog that selectively inhibits the 3 beta-hydroxysteroid dehydrogenase enzyme located in the adrenal cortex, thereby inhibiting the conversion of pregnenolone to progesterone. This inhibition blocks biosynthesis of glucocorticoids and 17 alpha-estradiol and 17 beta-estradiol, both of which may contribute to the elevation of adrenal androgens and, to a lesser extent, mineralocorticoids and sex hormones while maintaining precursor levels increase. The structural formula is shown above.

INDICATIONS: VETORYL Capsules are indicated for the treatment of pituitary-dependent hyperadrenocorticism and adrenal-dependent hypoadrenocorticism in dogs.

DOSEAGE AND ADMINISTRATION: Always provide the Client Information Sheet with prescription (see INFORMATION FOR DOG OWNERS).

1. Starting dose: The starting dose for the treatment of hyperadrenocorticism in dogs is 1-3 mg/lb (2.2-6.7 mg/kg) once a day. Start with the lowest possible dose based on body weight and available combinations of capsize sizes. VETORYL Capsules should be administered with food.

2. Action at 10-14 day evaluation (Table 1) After approximately 10-14 days at this dose, re-examine the dog and conduct a 4.5-hour post-dose ACTH stimulation test and serum biochemical tests (with particular attention to electrolytes, and renal and hepatic function). IF physical examination is acceptable, take action according to Table 1.

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