

The SmartPak Pharmacy

Dog & Cat Product Information Sheet

Vetoryl®

Common Drug Name – Trilostane

How Supplied by SmartPak – Vetoryl Capsules are available in 10, 30 and 60mg strengths, packaged in aluminum foil blister cards of 10 capsules with 3 cards per carton.

Category – Vetoryl Capsules are a synthetic steroid analogue.

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

Indications (Uses) – Vetoryl Capsules are for the treatment of pituitary-dependent hyperadrenocorticism in dogs (Cushing's). Vetoryl Capsules are also for the treatment of hyperadrenocorticism due to adrenocortical tumor in dogs.

Dosage and Administration – The starting dose is 1.0 – 3.0 mg/lb body weight (2.2 – 6.7mg/kg) once a day. Vetoryl Capsules should be administered with food. After approximately 10-14 days at the dose, dogs should be re-examined and a 4-6 hour post-dosing ACTH stimulation test performed. If physical examination is acceptable, dose should be discontinued, continued at the same amount, or increased depending on test results. Individual dose adjustments and close monitoring are essential. Dogs should be re-examined and ACTH stimulation test performed 10-14 days after every dose alteration. Care must be taken during dose increases to monitor the dog's clinical signs and serum electrolyte concentrations. Once daily administration is recommended. However, if clinical signs are not controlled for the full day, twice daily dosing may be needed using combinations of capsule sizes to slowly increase the dose. Long-Term Monitoring: Once an optimum dose of

Vetoryl Capsules has been reached, re-examine dogs at 30 days, 90 days and every 3 months thereafter. At a minimum, this monitoring should include a thorough history and physical examination, ACTH stimulation test and serum biochemical tests. A post-ACTH stimulation test resulting in a cortisol of <1.45ug/dl, with or without electrolyte abnormalities, may precede the development of clinical signs of hypoadrenocorticism. Good control is indicated by favorable clinical signs as well as post-ACTH serum cortisol of 1.45 – 9.1 ug/dl. If the ACTH stimulation test is <1.45ug/dl and/or if electrolyte imbalances characteristic of hypoadrenocorticism are found, Vetoryl Capsules should be temporarily discontinued until recurrence of clinical signs consistent with hyperadrenocorticism and test results return to normal. Vetoryl Capsules may then be re-introduced at a lower dose. Stop therapy and contact your veterinarian in the event of adverse reactions or unusual developments.

Contraindications – The use of Vetoryl Capsules is contraindicated in dogs that have demonstrated hypersensitivity to trilostane. Do not use Vetoryl Capsules in animals with primary hepatic disease or renal insufficiency. Do not use in pregnant dogs. Studies conducted with trilostane in laboratory animals have shown teratogenic effects and early pregnancy loss.

Human Warnings – Not for human use. Keep out of reach of children. Wash hands after use. Do not empty capsule contents and do not attempt to divide the capsules. Do not handle the capsules if pregnant or if trying to conceive. Trilostane is associated with teratogenic effects and early pregnancy loss in laboratory animals. In the event of accidental ingestion/overdose, seek medical

advice immediately and take the labeled container with you.

Warnings – In case of overdosage, symptomatic treatment of hypoadrenocorticism with corticosteroids, mineralocorticoids and IV fluids may be required. ACE inhibitors should be used with caution with Vetoryl Capsules, as both drugs have aldosterone-lowering effects which may be additive, impairing the patients' ability to maintain normal electrolytes, blood volume and renal perfusion. Potassium sparing diuretics should not be used with Vetoryl Capsules, as both drugs have the potential to inhibit aldosterone, increasing the likelihood of hyperkalemia.

Precautions – Hypoadrenocorticism can develop at any dose of Vetoryl Capsules. In some cases, it may take months for adrenal function to return and some dogs never regain adequate adrenal function. A small percentage of dogs may develop corticosteroid withdrawal syndrome within 10 days of starting treatment. This phenomenon results from acute withdrawal of circulating glucocorticoids; clinical signs include weakness, lethargy, anorexia and weight loss. These clinical signs should be differentiated from an early hypoadrenocortical crisis by measurement of serum electrolyte concentrations and performance of an ACTH stimulation test. Corticosteroid withdrawal syndrome should respond to cessation of Vetoryl Capsules and restarting at a lower dose. Mitotane treatment will reduce adrenal function. Experience in foreign markets suggests that when Mitotane therapy is stopped, an interval of at least one month should elapse before the introduction of Vetoryl Capsules. It is important to wait for both the recurrent of clinical signs consistent with hyperadrenocorticism and a post-ACTH cortisol level of >9.1 ug/dl before treatment with Vetoryl Capsules is initiated. Close monitoring of adrenal function is advised, as dogs previously treated with Mitotane may be more responsive to the effects of Vetoryl

Capsules. The safe use of this drug has not been evaluated in lactating dogs and males intended for breeding.

Adverse Reactions (Side Effects) – The most common adverse reactions reported are poor/reduced appetite, vomiting, lethargy/dullness, diarrhea and weakness. Occasionally, more serious reactions, including severe depression, hemorrhagic diarrhea, collapse, hypoadrenocortical crisis or adrenal necrosis/rupture may occur, and may result in death. Serious adverse reactions associated with this drug can occur without warning and in rare situations results in death. Discontinue Vetoryl Capsules and contact your veterinarian immediately if signs of intolerance are observed. Periodic follow-up for all dogs during administration of Vetoryl Capsules is important.

Storage Conditions: Store at controlled room temperature 25C (77F) with excursions between 15 – 30C (59 – 86F) permitted.

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