



Animal & Veterinary

VETORYL (trilostane) Capsules Letter - Veterinarians

September 11, 2009

Dear Veterinarian:

We are writing to you about the recent approval by the U.S. Food and Drug Administration (FDA) of VETORYL (trilostane) Capsules for the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease) in dogs. Please see the approval announcement at

<http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm150265.htm>.

VETORYL, distributed by Dechra, Ltd., is available in the U.S. in 10, 30, and 60 mg strength capsules. It is the only FDA-approved animal drug that contains trilostane as the active ingredient. Now that VETORYL is approved and available for veterinary use in the U.S., trilostane should not be imported from other countries or compounded from bulk.

Each FDA-approved animal drug goes through a rigorous evaluation process, and prior to approval, is clinically tested for safety and effectiveness in the target animal species. In addition, the FDA thoroughly inspects and evaluates the adequacy of the manufacturing process to ensure that the drug's identity, strength, quality, and purity are preserved. The FDA continues to monitor the drug's quality and safety after it is approved. An animal drug that is compounded from bulk drug ingredients is not FDA-approved, and therefore, the safety and effectiveness of the compounded drug, as well as the adequacy of the manufacturing process, have not been evaluated.

In prescribing FDA-approved VETORYL to treat Cushing's disease, you are providing your clients and their dogs with the only trilostane product that has demonstrated safety and effectiveness in dogs and whose manufacturing process met the FDA's standards for quality, purity, and potency.

You may have specific patients that require trilostane in strengths or forms that are not offered by VETORYL. In these limited cases, trilostane can only be legally compounded by using FDA-approved VETORYL as the starting material. Additional requirements and information on legal animal drug compounding are available in Title 21, Code of Federal Regulations, Section 530.13 (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=530&showFR=1>).

At the FDA's Center for Veterinary Medicine (CVM), we are committed to promoting and protecting animal health by ensuring that safe and effective drugs are available for veterinary use.

For more information, please contact the Communications Staff at CVM at 240-276-9300 or CVMHomeP@cvm.fda.gov.

Sincerely,

The FDA's Center for Veterinary Medicine

Vetoryl® vs. Lysodren®



	Vetoryl (trilostane)	Lysodren (mitotane)
FDA Veterinary Approval	YES	NO
Proven Safety & Efficacy in Dogs	YES	NO
Easy Treatment Regime	YES – daily capsule	NO – induction phase/maintenance
Mode of Action	Enzyme Inhibitor	Adrenal Cytotoxic Agent
Reversible	YES	NO
Low Stocking Cost	YES – 30 day supply	NO – bottle of 100 tablets (\$500+)
Long Term Availability	YES	Uncertain
Veterinary Technical Support	YES	NO

VETORYL® Capsules (trilostane)

10 mg, 30 mg, and 60 mg strengths

Adrenocortical suppressant for oral use in dogs only

BRIEF SUMMARY (For Full Prescribing Information, see package insert.)

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

DESCRIPTION: VETORYL is an orally active synthetic steroid analogue that blocks production of hormones produced in the adrenal cortex of dogs.

INDICATIONS: VETORYL Capsules are indicated for the treatment of pituitary-dependent hyperadrenocorticism in dogs. VETORYL Capsules are indicated for the treatment of hyperadrenocorticism due to adrenocortical tumor in dogs.

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.

WARNINGS: In case of overdosage, symptomatic treatment of hypoadrenocorticism with corticosteroids, mineralocorticoids and intravenous fluids may be required. Angiotensin-converting enzyme (ACE) inhibitors should be used with caution with VETORYL Capsules, as both drugs have aldosterone-lowering effects which may be additive, impairing the patient's ability to maintain normal electrolytes, blood volume and renal perfusion. Potassium-sparing diuretics (e.g., spironolactone) should not be used with VETORYL Capsules as both drugs have the potential to inhibit aldosterone, increasing the likelihood of hyperkalemia.

HUMAN WARNINGS: Keep out of reach of children. Not for human use. 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.

PRECAUTIONS: Hypoadrenocorticism can develop at any dose of VETORYL Capsules. A small percentage of dogs may develop corticosteroid withdrawal syndrome within 10 days of starting treatment. Mitotane (o,p'-DDD) 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. The use of VETORYL Capsules will not affect the adrenal tumor itself. Adrenalectomy should be considered as an option for cases that are good surgical candidates.

ADVERSE REACTIONS: 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.

