Product Name: **VETORYL 120 MG CAPSULES**
APVMA Approval No: **60618/115914**

RLP
APPROVED

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Label Name:	VETORYL 120 MG CAPSULES

Signal Headings:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY

Constituent Statements:	Each capsule contains 120 mg TRILOSTANE

Claims:	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's syndrome) in dogs.

Net Contents:	30 capsules

Directions for Use:	

Restraints:	

Contraindications:	This product is contraindicated in animals suffering from primary hepatic disease and/or renal insufficiency. This product is contraindicated in pregnant or nursing bitches or in any animals intended for breeding. The 120 mg capsule is contraindicated in animals weighing less than 20 kg. This product is contraindicated in dogs weighing less than 3 kg.

Precautions:	An accurate diagnosis of hyperadrenocorticism is essential. As the majority of cases of hyperadrenocorticism are diagnosed in dogs between the ages of 10-15 years, other pathological processes are frequently present. It is particularly important to screen cases for primary hepatic disease and renal insufficiency as the product is contraindicated in these cases. The presence of diabetes mellitus and hyperadrenocorticism together requires specific monitoring. If a dog has previously been treated with mitotane, its adrenal function will have been reduced. Experience in the field suggests that an interval of at least a month should elapse

	between cessation of mitotane and the introduction of trilostane. Close monitoring of adrenal function is advised, as dogs may be more susceptible to the effects of trilostane. The product should be used with extreme caution in dogs with pre-existing anaemia as further reductions in packed-cell volume and haemoglobin may occur. Regular monitoring should be undertaken. Trilostane may decrease testosterone synthesis and has anti-progesterone properties. The possibility of interactions with other medicinal products has not been specifically studied. Given that hyperadrenocorticism tends to occur in older dogs, many will be receiving concurrent medication. The risk of hyperkalaemia developing should be considered if trilostane is used in conjunction with potassium-sparing diuretics or ACE inhibitors. The concurrent use of such drugs should be subject to a risk-benefit analysis by the veterinary surgeon, as there have been a few reports of deaths (including sudden death) in dogs when treated concurrently with trilostane and an ACE inhibitor. A sudden reduction in serum cortisol may cause malaise and weakness, or may unmask arthritis or dermatoses. Caution should be used in treating animals which show clinical signs of arthritis with therapies such as NSAIDs which may also potentiate or precipitate renal disease or exacerbate existing problems that aged hyperadrenocorticoid dogs may have. Concomitant use of NSAIDs and other anti-inflammatories with trilostane has not been specifically studied. Therapies for osteoarthritis that are less likely than NSAIDs to cause renal injury should be considered in dogs receiving trilostane.

Side Effects:	Adverse reactions: Corticosteroid withdrawal syndrome or hypocortisolaemia should be distinguished from hypoadrenocorticism by evaluation of serum electrolytes. Signs associated with iatrogenic hypoadrenocorticism, including weakness, lethargy, anorexia, vomiting and diarrhoea may occur, particularly if monitoring is not adequate. Signs are generally reversible within a variable period following withdrawal of treatment. Acute Addisonian crisis (collapse) may also occur. Lethargy, vomiting, diarrhoea and anorexia have been seen in dogs treated with trilostane in the absence of evidence of hypoadrenocorticism. There have been occasional isolated reports of adrenal necrosis in treated dogs which may result in hypoadrenocorticism. Subclinical renal dysfunction may be unmasked by treatment with the product. Treatment may unmask arthritis or dermatoses due to a reduction in endogenous corticosteroid levels. A small number of reports have been received of sudden death during trilostane treatment. Other mild, rare, adverse effects include ataxia, hypersalivation, bloating, muscle tremors and skin changes. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. Overdosage: Overdose may lead to signs of hypoadrenocorticism. Treatment should be withdrawn and supportive therapy, including corticosteroids, correction of electrolyte imbalances and fluid therapy may be indicated depending on clinical signs. In cases of acute overdosage, induction of emesis followed by administration of activated charcoal may be beneficial. Any iatrogenic adrenocortical insufficiency is usually quickly reversed following cessation of treatment. However in a small percentage of dogs, effects may be prolonged. Symptomatic treatment or appropriate replacement therapy should be initiated. Following a one week withdrawal of trilostane treatment, treatment should be reinstated at a reduced dose rate.

Dosage and Administration:	Administer orally, once daily, with food. The starting dose for treatment is approximately 2 - 6 mg/kg, based on available combinations of capsule sizes. Start with the lowest possible dose based on body weight and available combinations of capsule sizes. Titrate the dose according to individual response, as determined by monitoring (see below). If a dose increase is required, use combinations of capsule sizes to slowly increase the once daily dose. A wide range of capsule sizes enables optimum dosing for the individual dog. Administer the lowest dose necessary to control the clinical signs.

	Ultimately, if clinical signs are not adequately controlled for an entire 24 hour inter-dose period, consider increasing the total daily dose by up to 50% and dividing it equally between morning and evening doses. Do not divide or open capsules. A small number of animals may require doses significantly in excess of 10 mg /kg bodyweight per day. In these situations appropriate additional monitoring should be implemented. 10 mg capsules should be used in dogs that require particularly small doses of trilostane, and to assist with dosage requirements. Only complete blister strips should be dispensed.

General Directions:	Where there is no apparent response to treatment, the diagnosis should be re-evaluated. Dose increases may be necessary. Monitoring: Samples should be taken for biochemistry (including electrolytes) and an ACTH stimulation test pre-treatment and then at 10 days, 4 weeks, 12 weeks, and thereafter every 3 months, following initial diagnosis and after each dose adjustment. It is imperative that ACTH stimulation tests are performed 4-6 hours post-dosing to enable accurate interpretation of results. Regular assessment of the clinical progress of the disease should also be made at each of the above time points. In the event of a non-stimulatory ACTH stimulation test during monitoring, treatment should be stopped for 7 days and then re-started at a lower dose. Repeat the ACTH stimulation test after a further 14 days. If the result is still non-stimulatory, stop treatment until clinical signs of hyperadrenocorticism recur. Repeat the ACTH stimulation test one month after re-starting treatment. Dogs should be monitored at regular intervals for primary hepatic disease, renal disease, and for diabetes mellitus. Subsequent close monitoring during treatment should be carried out. Particular attention should be paid to liver enzymes, electrolytes, urea and creatinine.

Withholding Periods:	

Trade Advice:	

Safety Directions:	

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre, phone Australia 131126.

First Aid Warnings:	

Additional User Safety:	Additional Safety Information: Product is harmful if swallowed. Do not swallow. Wash hands after use. Do not handle the capsules if pregnant or if trying to conceive. Trilostane may decrease testosterone synthesis and has anti-progesterone properties. Women who are pregnant or are intending to become pregnant should avoid handling the capsules. Wash hands with soap and water following accidental exposure and after use. The content of the capsules may cause skin and eye irritation and sensitisation. Do not divide or open capsules: in the event of accidental breakage of the capsules and contact of the granules with eyes or skin, wash immediately with plenty of water. If irritation persists, seek medical advice. In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

	People with known hypersensitivity to trilostane or any of the excipients should avoid contact with the product.

Environmental Statements:	

Disposal:	Dispose of empty containers by wrapping with paper and putting in garbage.

Storage:	Store below 25°C (air conditioning). Keep the blister strips in the carton.