Vetoryl®

120 mg Hard Capsules Trilostane

UK IE

Marketing authorisation holder:
Dechra Limited,
Snaygill Industrial Estate,
Keighley Road, Skipton,
North Yorkshire,
BD23 2RW, United Kingdom

Manufacturer responsible for batch release:
Dales Pharmaceuticals,
Snaygill Industrial Estate,
Keighley Road, Skipton,
North Yorkshire,
BD23 2RW, United Kingdom

Name of the veterinary medicinal product: Vetoryl 120 mg hard capsules Trilostane

Statement of the active substance and other ingredients: Hard gelatin capsules (ivory body/black cap) containing 120 mg of trilostane.

The ivory body is printed with the strength of the capsule.

Indications: For the treatment of pituitary-dependent and adrenal dependent hyperadrenocorticism in dogs.

Contraindication: Do not use in dogs weighing less than 20 kg.

Do not use in animals suffering from primary hepatic disease and/or renal insufficiency.

Do not use where there is suspected hypersensitivity to the active substance or to any of the excipients.

Do not use in pregnant or lactating bitches or in any animals intended for breeding.

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.

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 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 package leaflet, please inform your veterinary surgeon.

Target species: Dogs.

Dosage for each species, route and method of administration: Administer orally, once daily, with food. The starting dose for treatment is approximately 2 mg kg, based on 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 symptoms 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 per kg body weight per day. In these situations appropriate additional monitoring should be implemented.

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. Dosing in the morning is preferable as this will allow your veterinary surgeon to perform monitoring tests 4-6 hours following administration of the dose. 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.

Withdrawal period: Not applicable.

Special storage precautions: Keep out of the sight and reach of children.

Do not store above 25˚C. Keep the blister strips in the carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister after EXP.

The expiry date refers to the last day of that month.

Special warnings:

Special warnings for each target species:
An accurate diagnosis of hyperadrenocorticism is essential.

Where there is no apparent response to treatment, the diagnosis should be re-evaluated.

Dose increases may be necessary. Veterinarians should be aware that dogs with hyperadrenocorticism are at increased risk of pancreatitis. This risk may not diminish following treatment with trilostane.

Special precautions for use in animals:

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. Subsequent close monitoring during treatment should be carried out. Particular attention should be paid to liver enzymes, electrolytes, urea and creatinine.

User warnings:

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.

Interaction with other medicinal products and other forms of interaction:

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. In clinical studies, no interactions were observed.

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.

Overdose (symptoms, emergency procedures, antidotes): 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 the clinical signs. There were no mortalities following chronic administration at 36 mg/kg to healthy dogs, however mortalities may be expected if higher doses are administered to dogs with hyperadrenocorticism. 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.

Special precautions for the disposal of unused product or waste materials: Any unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: 20-11-2014

Other information: For animal treatment only. Symptomatic treatment of hypocortisolaemia may be required. Only complete blister strips should be dispensed.

UK: Vm 10434/4069 POM-V Prescription Only Medicine - Veterinarian	IE: VPA 10799/020/004 POM Prescription Only Medicine

To be supplied only on veterinary prescription.

Veterinary medicinal product authorised for use in UK and IE.

Packaged in 3 blisters of 10 capsules.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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