IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Vetoryl 20 mg hard capsules for dogs

PRODUCT SUMMARY

EU Procedure number	IE/V/0514/010/DX/001
Name, strength and pharmaceutical form	Vetoryl 20 mg hard capsules for dogs
Active substance(s)	Trilostane
Applicant	Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, Netherlands
Legal basis of application	Full application – in accordance with Article 8 of Regulation (EU) 2019/6.
Date of completion of procedure	30/09/2024
Target species	Dogs
Indication for use	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome).
ATC vet code	QH02CA01
Concerned Member States	AT, BE, HR, CZ, DK, FI, FR, DE, EL, HU, IT, LU, NL, NO, PL, PT, SK, SI, ES, SE, UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in the relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland. The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species.
The product is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars
The product contains 20 mg of the active substance trilostane and the excipients lactose monohydrate, maize starch, magnesium stearate, capsule shells (containing yellow iron oxide, black iron oxide, titanium dioxide and gelatin) and capsule inks.
The container/closure system is PVC-PVDC / aluminium blisters of 10 tablets in cartons of 30 capsules.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product
The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.
Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials
The active substance is Trilostane, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.
The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies
Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on Intermediate Products
Not applicable.

E. Control Tests on the Finished Product
The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability
Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.
Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information
Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This variation requiring assessment (VRA) was submitted to introduce a 20 mg hard capsule to the existing 'Vetoryl' range.
Reference is made to the information already presented and assessed in the context of the authorisation procedures for the authorised Vetoryl hard capsules (5 mg, 10 mg, 30 mg, 60 mg and 120 mg).
The safety aspects of this product are identical to the authorised Vetoryl hard capsules.
Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users and the environment.

III. SAFETY ASSESSMENT

Pharmacological Studies
No proprietary data were submitted, and reference is made to the information already presented and assessed in the context of the authorisation procedures for the authorised Vetoryl hard capsule (5 mg, 10 mg, 30 mg, 60 mg and 120 mg).

Toxicological Studies
No proprietary data were submitted, and reference is made to the information already presented and assessed in the context of the authorisation procedures for the authorised Vetoryl hard capsule (5 mg, 10 mg, 30 mg, 60 mg and 120 mg).

User Safety
No additional hazard, exposure, or risk to users of the 20 mg hard capsule, as compared to the authorised 120 mg hard capsule is anticipated.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product, as follows:

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 and show the package leaflet/label to the physician.
People with known hypersensitivity to trilostane or any of the excipients should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Environmental Risk Assessment
No additional risk to the environment will be posed by the 20 mg hard capsule, as compared to the authorised 120 mg hard capsule.

Conclusion
The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT

This variation requiring assessment (VRA) was submitted to introduce a 20 mg hard capsule to the existing 'Vetoryl' range.
Reference is made to the information already presented and assessed in the context of the authorisation procedures for the authorised Vetoryl hard capsules (5 mg, 10 mg, 30 mg, 60 mg and 120 mg).
The efficacy aspects of this product are identical to the authorised Vetoryl hard capsules.

IV.A Pre-Clinical Studies
Pharmacology
The applicant conducted *in vitro* dissolution studies at a range of physiologically relevant pH values to show equivalence between the proposed 20 mg hard capsule and the authorised 10 mg capsule. Therefore, the safety and efficacy profiles of the authorised range of Vetoryl capsules may be extrapolated to 'Vetoryl 20 mg hard capsule for dogs'.

Tolerance in the Target Species of Animals
The product literature accurately reflects the type and incidence of adverse effects (consistent with the authorised Vetoryl hard capsules) which might be expected.

IV.B Clinical Studies (pharmaceuticals and immunologicals)
No proprietary data are submitted, and reference is made to the information already presented and assessed in the context of the authorisation procedures for the authorised Vetoryl hard capsule (5 mg, 10 mg, 30 mg, 60 mg and 120 mg).

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.