Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Adrestan 10 mg hard capsules
Adrestan 30 mg hard capsules
Adrestan 60 mg hard capsules

Date Created: June 2016

PuAR correct as of 01/08/2018 when RMS was transferred to IE.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0583/001/DC UK/V/0583/002/DC UK/V/0583/003/DC
Name, strength and pharmaceutical form	Adrestan 10 mg hard capsules Adrestan 30 mg hard capsules Adrestan 60 mg hard capsules
Applicant	Dechra Limited Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW United Kingdom
Active substance	Trilostane
ATC Vetcode	QH02CA01
Target species	Dogs
Indication for use	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	27th January 2016.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Belgium, France, Germany, Ireland, Italy, The Netherlands, Portugal, Spain.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to those of Vetoryl 10 mg Hard Capsules for Dogs, Vetoryl 30 mg Hard Capsules for Dogs and Vetoryl 60 mg Hard Capsules for Dogs.

II. 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 of the product(s) is favourable.

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MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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