IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Adrestan 10 mg hard capsules for dogs

PRODUCT SUMMARY

EU Procedure Number	IE/V/0503/001 (formerly UK/V/0583/001)
Name, Strength, Pharmaceutical Form	Adrestan 10 mg hard capsules for dogs
Active Substances(s)	Trilostane
Applicant	Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, Netherlands
Legal Basis of Application	Informed consent application (Article 13c of Directive No 2001/82/EC)
Target Species	Dogs
Indication For Use	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.
ATC Code	QH02CA01
Date of completion of the original decentralised procedure	27 January 2016 (UK) 01 April 2016 (IE)
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Belgium, France, Germany, Ireland (now RMS), Italy, The Netherlands, Portugal, Spain. UK added via RMS change

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the 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 Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. 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 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.

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 of the product(s) is favourable.