Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Trilotab Flavoured 10mg Tablet for Dogs
Trilotab Flavoured 30mg Tablet for Dogs
Trilotab Flavoured 60mg Tablet for Dogs
Trilotab Flavoured 120mg Tablet for Dogs
Trilotab Flavoured 150mg Tablet for Dogs

Date Created: December 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Trilotab Flavoured 10mg Tablet for Dogs Trilotab Flavoured 30mg Tablet for Dogs Trilotab Flavoured 60mg Tablet for Dogs Trilotab Flavoured 120mg Tablet for Dogs Trilotab Flavoured 150mg Tablet for Dogs
Applicant	CP Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany
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).

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	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	18/9/2023

I. SCIENTIFIC OVERVIEW

This was determined a generic 'hybrid' application because changes to the strength with regard to the reference medicinal product have been made.

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, any reactions observed are indicated in the SPC.[1] 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 [2] 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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains trilostane and the excipients lactose monohydrate, pregelatinized starch, hydroxypropylcellulose, colloidal hydrated silica, sodium starch glycolate (Type A), magnesium stearate and chicken flavour.

The container/closure system consists of a coated PVC/aluminium foil blister pack. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of: dry mixing, granulation and compression.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The active substance is trilostane, an established active substance described in the ASMF. 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 have been provided.

The excipients, with the exception of chicken flavour, are described in Ph. Eur. and EU Food Directive. A separate specification for chicken flavour is acceptable.

II.C.4. Substances of Biological Origin

Scientific data and/or certificates of suitability issued by the EDQM have been provided and 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.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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 have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are those for: appearance, mass, uniformity, identification, dissolution and microbiological purity.

II.F. Stability

Stability data on the active substance have 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 have 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

Shelf life of the veterinary medicinal product as packaged for sale: 22 months
120 mg Tablets:
Shelf life of the veterinary medicinal product as packaged for sale: 34 months

Do not store above 25°C.
Any remaining portions of divided tablets should be returned to the opened blister and given at the next administration.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required as bioequivalence was demonstrated with the reference product.

Toxicological Studies

Not required due to the legal basis of the application.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:,

Accidental ingestion of the product can cause gastrointestinal effects, such as nausea and vomiting.
Avoid hand to mouth contact. To avoid accidental ingestion, especially by a child, unused tablet parts should be placed back into the blister and carton and carefully kept away from children. Part used tablets should be used at the time of the next dose.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or carton to the physician.
Wash hands with soap and water after use.

Trilostane may decrease testosterone synthesis and has anti-progesterone properties.
Women who are pregnant or are intending to become pregnant should avoid handling the product.

The product may cause skin and eye irritation. After contact of the product with eyes or skin, wash with plenty of water. If irritation persists, seek medical advice.

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to trilostane should avoid contact with the product. If you develop allergic symptoms such as a skin rash, swelling of the face, lips or eyes following exposure to the product, seek medical advice and show the package leaflet or label to the physician.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Not required due to the legal basis of the application.

IV.II. Clinical Documentation

Not required as above. A study was submitted to demonstrate bioequivalence to the reference product.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the products are favourable.

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.

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

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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