Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Tardastrex 10 mg/ml Suspension for Injection for Dogs and Cats

Date Created: June 2016

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0569/001/DC
Name, strength and pharmaceutical form	Tardastrex 10 mg/ml Suspension for Injection for Dogs and Cats
Applicant	Zoetis UK Limited 5th Floor, 6 St. Andrew Street London EC4A 3AE
Active substance	Delmadinone acetate
ATC Vetcode	QG03DX91
Target species	Cats and Dogs
Indication for use	The product is for use in male dogs and cats in the following indications: The treatment of hypersexuality (excessive or aberrant sexual behaviour, including vagrancy) not related to sociopathic disorders. The relief of prostatic hypertrophy whether benign, carcinomatous or when due to chronic inflammatory processes (in cases of the latter, relief cannot be expected unless appropriate accompanying therapy, such as corticosteroids or antibiotics is also instituted). For the treatment of circum-anal tumours. For the treatment of certain forms of aggressiveness, nervousness, epileptiform seizures and corticosteroid-resistant pruritus (developing into dermatoses and accompanied by alopecia).

MODULE 2

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

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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 completion of the original decentralised procedure	30th March 2016.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Croatia, Czech Republic, Hungary, Poland, Slovakia, Slovenia.

I. SCIENTIFIC OVERVIEW

This was an application for a generic product, submitted in accordance with Article 13 (1) of Directive 2001/82/EC as amended. The reference product is Tardak 10 mg/ml Suspension for Injection, marketed in the UK since April 1992. The proposed product and the reference product have been confirmed as identical, (both products are produced by the same Marketing Authorisation Holder). Bioequivalence was accepted.

The product is indicated for use in male dogs and cats for the treatment of hypersexuality, (excessive or aberrant sexual behavior, including vagrancy), not related to sociopathic disorders. It is also indicated for the relief of prostatic hypertrophy whether benign, carcinomatous or when due to chronic inflammatory processes (in cases of the latter, relief cannot be expected unless appropriate accompanying therapy, such as corticosteroids or antibiotics is also instituted). For the treatment of circum-anal tumours. The product may also be used for the treatment of certain forms of aggressiveness, nervousness, epileptiform seizures and corticosteroid-resistant pruritus (developing into dermatoses and accompanied by alopecia).

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto 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

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

favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTIUENTS

II.A. Composition

The product contains 10 mg/ml delmadinone acetate and the excipients benzalkonium chloride, disodium edetate, macrogol 4000, citric acid monohydrate, sodium citrate dihydrate, polysorbate 80, sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

The container/closure system consists of carton containing 10 ml colourless Type I glass vial with a blue halobutyl (siliconised) rubber bung and aluminium overseal. The particulars of the containers and controls performed are provided and conform to the regulation. The choice of the formulation and the presence of preservative are justified.

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

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 weighing of ingredients, production of the bulk solution, filtration and filling into vials.

II.C. Control of Starting Materials

The active substance is delmadinone acetate, an established non-pharmacopoeial 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 have been provided.

All excipients are monographed in the Ph. Eur. Packaging complies with the appropriate specifications.

II.C.4. Substances of Biological Origin

The applicant has submitted EMA Table A: ‘Materials of animal origin covered by the scope of the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products’ and a declaration of compliance.

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 include those for appearance, fill volume, pH, particle size, identification of active substance and related substances and sterility.

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 were provided for one trial batch and two commercial-scale batches of the proposed product suspension. Trials were performed on stored product and data provided on in-use stability in accordance with VICH[3] guidelines. A warning to protect the product from light is included in the SPC, as no studies were performed with regard to this respect.

G. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate container: 28 days.

Keep the vial in the outer carton in order to protect from light.

[3] VICH – International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1), and the proposed product is identical to the reference product, results of toxicological and pharmacological tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users and the environment.

III.A Safety Documentation

User Safety

A user risk assessment was provided in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety to users of the product:

- Preparations containing progestogens should be handled with care, particularly by women of childbearing age.
- Avoid contact with skin. Impervious gloves should be worn whilst administering this product.
- In case of contact with skin, wash off any product with soap and water. If eye exposure occurs, flush immediately with water.
- In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Environmental Safety

A Phase I Environmental Risk Assessment was provided. The product us for use in individual companion animals, and is not expected to pose a risk to the environment when used as recommended.

IV CLINICAL DOCUMENTATION

As this is a generic application according to Article 13 (1), and the proposed product was established as being identical to the reference product, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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

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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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