Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

INDUPART 75 µg/mL solution for injection for cattle, pigs and horses

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V0203/001/DC
Name, strength and pharmaceutical form	INDUPART 75 µg/mL solution for injection for cattle, pigs and horses
Applicant	VETPHARMA ANIMAL HEALTH, S.L.
Active substance(s)	D-Cloprostenol sodium
ATC Vet code	QG02AD90
Target species	Cattle (cows), pigs (sows) and horses (mares)
Indication for use	See SPC

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 44 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	24/04/2014
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	AT, BG, BE, CZ, DE, DK, EE, HU, IE, LU, LT, LV, NL, PL, PT, SK, RO, UK

I. SCIENTIFIC OVERVIEW

For public assessment reports for the first authorisation in a range*:*

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 slight reactions observed are indicated in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals 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 risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains D-cloprostenol sodium and Chlorocresol, Ethanol 96%, Sodium hydroxide, Citric acid anhydrous and water for injections.

The container/closure system is type I colourless glass vials closed with bromobutyl rubber stopper and sealed with aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the presence of preservative are justified.

The product is a novel 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 from a licensed manufacturing site.

C. Control of Starting Materials

The active substance is D-cloprostenol sodium, 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 have been provided.

ASMF reference: AA/0072/13 from Spanish Agency (AEMPS).

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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.

E. Control on intermediate products (pharmaceuticals)

Not applicable.

F. 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 MEVET S.A.U. have been provided demonstrating compliance with the specification.

G. 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.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety and residues tests are not required.

The safety and residues aspects of this product are identical to the reference product.

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 / the environment / consumers.

III.A Safety Testing

Pharmacological, toxicological and other safety studies

Since this is an application under Article 13(1) of Directive 2001/82/EC, as amended, the applicant is not required to provide data regarding the pharmacology, toxicology or other safety studies performed with the active ingredient.

User Safety

As this is a generic application according to Article 13, and presents identical risks to the user as those of the reference product, warnings and precautions as listed on the product literature are the same as for the reference product and are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Residue Studies

No residue studies are provided because the application has been submitted in accordance with article 13(1) of Directive 2001/82/EC and equivalence with the reference product has been demonstrated.

MRLs

Cloprostenol is listed in “Table 1: Allowed substances” of Council Regulation 37/2010. No MRLs are required for this substance.

Withdrawal Periods

Based on the data requirements for this application and taking into account the "Guideline on safety and residue data requirements for veterinary medicinal products intended for minor uses or minor species" (EMEA/CVMP/SWP/66781/2005), the resulting withdrawal periods, as advised in the SPC and package leaflet are as follows:

- Cattle: Meat and offal: Zero days
  Milk: Zero hours
- Pigs: Meat and offal: 1 day
- Horses: Meat and offal: 2 days
  Milk: Zero hours

IV. CLINICAL ASSESSMENT (EFFICACY)

For generics, insert in the relevant sections as appropriate:

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, 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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 veterinary Heads of Agencies website (www.hma.eu).

This section 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.

None