Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

Cyclix Porcine Solution for Injection (87.5 microgram/ml)

Date: 23 November 2011

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0112/001/MR
Name, strength and pharmaceutical form	Cyclix Porcine, 87,5 µg/ml, solution for injection
Applicant	VIRBAC 1ère avenue – 2065 m 06516 Carros Cedex FRANCE
Active substance(s)	Cloprostenol sodium
ATC Vetcode	QG02AD90
Target species	Sow
Indication for use	Induction or synchronisation of farrowing (within 16 to 34 hours) from day 113 of pregnancy onwards (day 1 of pregnancy is the last day of natural or artificial insemination).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original Mutual recognition procedure Repeat use Procedure	January 2006 30 August 2011
Date product first authorised in the Reference Member State (MRP only)	30 May 2005
Concerned Member States	AT, BE, BG, CZ, ES, FR, HU, IE, IT, LU, NL, PL, PT, SK, UK

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I. SCIENTIFIC OVERVIEW

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 safety / efficacy aspects of this product are identical to Planate (Suimate). The initial application for Planate (Suimate) was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

Cyclix Porcine is a colourless, sterile, aqueous solution for injection, containing Cloprostenol sodium (0.092 mg / ml) in an isotonic citrate buffer.

Qualitative Composition	Quantitative composition	Reference to analytical quality
Active Substance (A.S.)	"*Cyclix Porcine*"	
Cloprostenol Sodium equivalent to Cloprostenol	0.0920 mg 0.0875 mg	BP Veterinary
Excipients	q.s. . to 1 ml	Ph. Eur. Ph. Eur.
Water for injections, bulk		

The container/closure system is made of white blow-moulded *glass* (hydrolytic class I) and closed by 20 mm *halogenated butyl* rubber stoppers (Ph. Eur.) fitted with aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

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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.
The product is manufactured using conventional manufacturing techniques. Validation data of several batches has been presented. The submitted data suggests that the manufacturing process is well under control.

C. Control of Starting Materials

The active substance is Cloprostenol Sodium, an established active substance described in the British Veterinary Pharmacopoeia. 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.

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

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

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 sites 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.

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.

The claim of 28 days stability after broaching of the vials is based on the demonstration of stability for a batch broached and stored 28 days at +25°C.

H. Genetically Modified Organisms

Not applicable

J. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 of Directive 2001/82 as amended, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

The safety 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.

User Safety

Warnings and precautions as listed on the product literature 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. The assessment concluded that the product is not expected to pose a risk for the environment when used in accordance with the SPC.

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 depletion studies were conducted because a bioequivalence study confirms the essential similarity of Cyclix Porcine and the approved reference product Planate.

MRLs

Cloprostenol is listed in Table 1 of Commission Regulation (EU) No 37/2010. No MRLs were set.

Withdrawal Periods

Based on the data provided above, a withdrawal period of 2 days for meat in pig is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 of Directive 2001/82 as amended, 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.

Periodic Safety Update Reports (PSUR)

Since marketing authorisation of Cyclix Porcine injection for solution in Germany in May 2005, a Periodic Safety Update Report (PSUR) covering the period from June 1, 2005 to August 31, 2009 had been presented by the applicant in December 2009.

During that time a calculated number of 2 064 750 animals had been treated with the product. No reports on suspected adverse drug reactions (SADR) had been received. No data warranting a reassessment of the safety profile of Cyclix Porcine had been published. It was, therefore agreed with the applicant that the risk/benefit ratio for the product was unchanged and that no revision of the product literature was necessary.

The submission date for the next PSUR is October 2012.

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 Heads of Veterinary Medicinal 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>

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