Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bioestrovet Swine 0.0875 mg/ml Solution for Injection for Pigs

Date Created: May 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bioestrovet Swine 0.0875 mg/ml Solution for Injection for Pigs
Applicant	Vetoquinol UK Ltd Vetoquinol House, Great Slade Buckingham Industrial Park Buckingham Buckinghamshire MK18 1PA
Active substance	Cloprostenol
ATC Vetcode	QG02AD90
Target species	Pigs
Indication for use	In sows and gilts: - Induction of farrowing from day 114 of pregnancy onwards (day 1 of pregnancy is the last day of insemination)

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	24/05/2022

I. SCIENTIFIC OVERVIEW

This application is for a generic product based on the reference product, Planate 0.0875 mg/ml Solution for Injection, marketed by Intervet UK Ltd.

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

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains cloprostenol and the excipients benzyl alcohol, sodium citrate, anhydrous citric acid, sodium chloride, water for injections.

The container/closure system consists of Type I glass vials, closed with a bromobutyl rubber stopper coated with an ETFE (ethylene tetrafluoroethylene) film and sealed with an aluminium seal and a polypropylene cap. 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.

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 cloprostenol, 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.

The methods are described in the ASMF

All excipients and packaging are described in the European Pharmacopoeia.

II.C.4. Substances of Biological Origin

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

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.

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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days
Keep the vial in the outer carton in order to protect from light.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required as this is a generic application.

Toxicological Studies

Not required as this is a generic application.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that cloprostenol may impair fertility, may cause harm to the unborn child and can be toxic if swallowed. In humans, it is known to cause vomiting, nausea, and diarrhoea due to the stimulatory action on smooth muscle of alimentary tract. Intense bronchospasm in asthmatic patients was observed due to the effect on the smooth muscle of respiratory tract. This substance is also considered to be irritant to the skin, the eyes, and the respiratory tract, and is a possible sensitiser. In addition, the excipient benzyl alcohol has also been identified as a skin and eye irritant.

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:,

- Prostaglandins of the F2-α type, such as cloprostenol, can be absorbed through the skin and mucous membranes and may cause bronchospasm or miscarriage.
- Care should be taken when handling the product to avoid self-injection or skin contact.
- Pregnant women, women of child-bearing age, asthmatics and people with bronchial or other respiratory problems must avoid any contact with the product.
- This product may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the product.
- Wear disposable impervious gloves when administering the product.
- Wash hands after use.
- Accidental spillage on the skin should be washed off immediately with soap and water.
- In case of accidental self-injection or spillage onto the skin, seek medical advice and show the package leaflet or label to the physician.
- Should shortness of breath occur, seek medical advice immediately and show the package leaflet or label to the physician. Do not eat, drink or smoke while handling the product.

Environmental Safety

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

Phase I:

The initial predicted environmental concentration (PEC) in soil is less than 100 µg/kg. A Phase II ERA was not required.

III.B.2 Residues documentation

Residue Studies

No residue depletion studies were conducted because this is a generic application.

Withdrawal Periods

Based on the data provided, a withdrawal period of 2 days for meat and offal in pigs are justified.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Not required as this is a generic application and studies demonstrated bioequivalence between Bioestrovet and Planate.

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 is 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.

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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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