Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Luteoplan 0.25 mg/ml Solution for Injection

Date Created: January 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Luteoplan 0.25 mg/ml Solution for Injection
Applicant	Syn Vet-Pharma Ireland Limited 7A Durands Court 45 Parnell Street X91 P381 Ireland
Active substance	Cloprostenol
ATC Vetcode	QG02AD90
Target species	Cattle and Horses
Indication for use	Cattle (heifers, cows): • Synchronisation or induction of oestrus; • Treatment of ovarian dysfunction (persistent corpus luteum, luteal cyst); • Treatment of uterine disorders related to a functioning or persistent corpus luteum (endometritis, pyometra); • Induction of abortion until day 150 of pregnancy; • Expulsion of mummified foetuses; • Induction of parturition Horses (mares): • Induction of luteolysis with a functional corpus luteum

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	18/10/2023

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, any reactions observed are indicated in the SPC.[1] 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 [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.

The quality / safety / efficacy aspects of this product is/are identical to Estrumate 250 microg/ml solution for injection. The initial application for Estrumate 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 clorocresol, citric acid anhydrous, sodium hydroxide, anhydrous ethanol and water for injections.

The container/closure system consists of type I amber glass vials. 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.

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

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: mixing, dissolution and filtration.

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 cloprestenol, 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.

All excipients and packaging comply with Ph. Eur.

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. Control tests on the finished product are those for: appearance, particulate contamination, clarity, colour, identification, assay, related substances, pH, density, tightness 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 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: 2 years
Shelf life after first opening the immediate packaging: 28 days

This veterinary medicinal product does not require any special temperature storage conditions.
This veterinary medicinal product should be stored upright.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required due to the legal basis of the application.

Toxicological Studies

Not required.

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:

- Prostaglandins of the F2α type, such as cloprostenol, can be absorbed through the skin and may cause bronchospasm or miscarriage.
- Care should be taken when handling the veterinary medicinal product to avoid self-injection or skin contact.
- Pregnant women, women of child-bearing age, asthmatics and people with bronchial or other respiratory problems should avoid any contact with the veterinary medicinal product.
- Wear disposable impervious gloves when administering the veterinary medicinal product.
- Accidental spillage on the skin should be washed off immediately with soap and water.
- If accidental contact with eyes occurs, rinse the affected eyes thoroughly with clean, fresh water.
- In case of accidental self-injection or spillage onto the skin seek medical advice immediately, particularly as shortness of breath may occur, and show the package leaflet or label to the physician.
- Do not eat, drink or smoke while handling the veterinary medicinal product.
- Chlorocresol may cause irritation and allergic reactions. People with known hypersensitivity to chlorocresol should administer the veterinary medicinal product with caution.

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

Not required as to bioequivalence has been established with the reference product.

Withdrawal Periods

Based on the data provided, a withdrawal period of 1 day for meat in cattle and zero hours for milk are justified.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Not required

IV.II. Clinical Documentation

Not required.

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.

(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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