Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Synchromate 0.25mg/ml, Solution for Injection for Cattle and Horses

Date Created: December 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Synchromate 0.25mg/ml, Solution for Injection for Cattle and Horses
Applicant	Alivira Animal Health UK Ltd Hygeia Building, Rear Ground Floor 66-68 College Road Harrow Middlesex HA1 1BE
Active substance	Cloprostenol
ATC Vetcode	QG02AD90
Target species	Cattle and Horses

Indication for use	Cattle:
	• Suboestrus or non-detected oestrus
	• Induction of parturition
	• Termination of normal pregnancy
	• Termination of abnormal pregnancy
	  ○ Mummified foetus
	  ○ Hydrops of the foetal membranes
	• Chronic endometritis (pyometra)
	• Ovarian luteal cysts
	• Controlled breeding
	Horses:
	• Induction of luteolysis following early foetal death and resorption
	• Termination of persistent dioestrus
	• Termination of pseudopregnancy
	• Treatment of lactation anoestrus
	• Establishing oestrous cycles in barren/maiden mares.

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	2/11/2022

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Estrumate 250µg/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 sodium and the excipients chlorocresol, citric acid monohydrate, ethanol 96%, sodium chloride, sodium citrate and water for injection.

The container/closure system consists of clear glass Type I vials closed with rubber stoppers and aluminium seals. 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: mixing, dissolution, filtration and sterilised.

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 sodium, an established active substance described in the European 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.

ASMF has been provided.

All excipients meet the requirements of the relevant Ph. Eur. monographs.

The packaging also complies.

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 sites have been provided demonstrating compliance with the specification. Control tests on the finished product are those for: appearance, colour, pH density, refractive index, particle contamination, extractable volume, identification of cloprostenol, identification of chlorocresol, assay of cloprostenol sodium, assay of chlorocresol, impurities, microbiological quality 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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 36 months
Shelf life after first opening the immediate packaging: 28 days

This veterinary medicinal product does not require any special temperature storage conditions.
Keep vial in the outer carton in order to protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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 due to the legal basis of the application.

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:,

Direct contact with skin or mucous membranes of the user should be avoided. Prostaglandins of the F2α type may be absorbed through the skin 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 childbearing age, asthmatics and persons with other respiratory tract diseases should exercise caution when handling cloprostenol. Those persons should avoid contact or wear disposable gloves during administration of the product. Accidental spillage on the skin should be washed immediately with soap and water. The possible incidence of bronchospasm with the product is unknown. Should shortness of breath result from accidental inhalation or injection, seek urgent medical advice and show the doctor this warning. Wash hands after use.

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

Not required due to the legal basis of the application.

Withdrawal Periods

Cattle
Meat: 1 day
Milk: zero hours

Horses
Not to be used in horses intended for human consumption.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

Not required due to the legal basis of the application.

Tolerance in the Target Species

Tolerance studies were not required due to the legal basis of the application.

IV.II. Clinical Documentation

Not submitted due to the legal basis of the application.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that 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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