DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

# Agencia Española de Medicamentos y Productos Sanitarios

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

**DECENTRALISED PROCEDURE**

## PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

## Synchromate 0.25mg/ml solution for injection for cattle, pigs and horses

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# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| EU Procedure number | ES/V/0411/001/DC |
| Name, strength and pharmaceutical form | Synchromate 0.25mg/ml solution for injection for cattle, pigs and horses |
| Applicant | Alivira Animal Health Limited<br>16 Glenoaks Close, Glenconner<br>Clonmel, Co Tipperary<br>E91 T8Y6<br>Ireland |
| Active substance(s) | Cloprostenol 0.25 mg |
| ATC Vetcode | QG02AD90 |
| Target species | Cattle (cows), pigs (sows) and horses (mares) |
| Indication for use | - Subestrous or silent oestrus<br>- Treatment of luteal cysts.<br>- Induction and synchronization of estrus<br>- Termination of pregnancy until day 150 of pregnancy<br>- Expulsion of mummified foetus<br>- Induction of parturition after 270 days of pregnancy<br>- Adjuvant treatment in chronic endometritis and pyometra.<br><br>**Pigs (Sows):**<br><br>- Induction of labour or synchronization of labour from day 114 of pregnancy (the last insemination day counted as the 1st day of pregnancy).<br><br>**Horses (Mares):**<br><br>- Induction of luteolysis.<br>- Treatment of persistent dioestrus.<br>- Treatment of pseudo-pregnancy.<br>- Treatment of lactation anestrus.<br>- Induction of estrous cycle.<br>- Induction of labour after 320 days of pregnancy. |

# 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 13.1 of Directive 2001/82/EC as amended. |
| Date of completion of the original decentralised procedure | Day 210: 27/07/2022 |
| Date product first authorised in the ReferenceMemberState (MRP only) | N/A |
| Concerned Member States for original procedure | BE, HU, IT, NL, PL, PT, RO |

## 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 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. Qualitative and quantitative particulars*

The product contains 0.25 mg/ml of cloprostenol (as 0.263 mg/ml cloprostenol sodium) as active substance and chrorocresol as preservative and citric acid monohydrate, ethanol 96%, sodium chloride, sodium citrate and water for injections as excipients.

The container/closure system is clear glass vials of type I with bromo butyl stopper and aluminum cap (for 20 ml) and clear glass vials of type I with laminated elastomeric bromo butyl stopper and aluminum cap (for 10 ml)

The choice of the formulation and 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.

### *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 in accordance with the European Pharmacopoeia and relevant European guidelines.

### *C. Control of Starting Materials*

The active substance is Cloprostenol sodium an established substance described in the 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.

Scientific data 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.

### *D. Control on intermediate products*

Not applicable.

### *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<s> have been provided demonstrating compliance with the specification.

### *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.

The claim of 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored.

### *G. Other Information*

Not applicable

## 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 and consumers.

### *III.A Safety Testing*

#### *Pharmacological Studies*

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

#### *Toxicological Studies*

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

#### *User Safety*

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the product does not present any greater risk to the user than that presented by the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

#### *Environmental Risk Assessment*

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required. The use of the product does not pose a risk for the environment.

### *III.B Residues documentation*

***Residue Studies***

No residue depletion studies were conducted because this application is for a generic product, submitted in accordance with Article 13 of Directive 2001/82/EC, and bioequivalence with the reference product has been demonstrated.

***MRLs***

Cloprostenol is listed in table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs (µg/kg) | Target tissues | Other provisions |
|---|---|---|---|---|---|
| Cloprostenol | Not applicable | Bovine, porcine, caprine, *Equidae* | No MRL required | Not applicable | No entry |
| R-Cloprostenol | Not applicable | Bovine, porcine, caprine, *Equidae* | No MRL required | Not applicable | No entry |

***Withdrawal Periods***

Based on the data provided above, the withdrawal periods for the proposed product are the same as those of the reference product:

**Cattle (cows):**
Meat and offal: 2 days
Milk: Zero days

**Pigs (sows):**
Meat and offal: 2 days

**Horses (mares):**
Meat and offal: 28 days

## IV. CLINICAL ASSESSMENT (EFFICACY)

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**