Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Seclaris DC 250 mg Intramammary Suspension for Dry Cows

Date Created: 7th March 2018

PuAR correct as of 18/12/2018 when RMS was transferred to FR.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0621/001/DC
Name, strength and pharmaceutical form	Seclaris DC 250 mg Intramammary Suspension for Dry Cows
Applicant	Ceva Animal Health Ltd
Active substance(s)	Cephalonium
ATC Vetcode	QJ51DB90
Target species	Cattle
Indication for use	For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Trueperella pyogenes*, *Escherichia coli* and *Klebsiella* spp susceptible to cefalonium.

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 'hybrid' application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of conclusion of the decentralised procedure	20th September 2017
Date product first authorised in the Reference Member State (MRP only)	N/A

I. SCIENTIFIC OVERVIEW

This was a generic 'hybrid' application in accordance with Article 13(3) of Directive 2001/82/EC, as amended. This was determined a generic 'hybrid' because the product acts locally and therefore bioequivalence to the reference product cannot be demonstrated. The reference product is Cepravin Dry Cow 250 mg Intramammary Suspension, authorised in the UK since January 1993.

The product is indicated for the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Trueperella pyogenes*, *Escherichia coli* and *Klebsiella* spp susceptible to cefalonium. The product is administered via either short or full nozzle intramammary administration.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto 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.

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

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains 250 mg cefalonium (as cefalonium dehydrate) and the excipients aluminium stearate and liquid paraffin.

The container/closure system consists of polyethylene syringes with polyethylene caps. The product comes in pack sizes of 20 or 72 intramammary syringes. The packs also contain either 20 or 72 alcohol impregnated cleaning towels. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence 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 cefalonium, an established active substance described in the British Veterinary Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice and in accordance with an Active Substance Master Files (ASMF).

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. Both excipients are manufactured in accordance with 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 sites have been provided demonstrating compliance with the specification. Control tests on the finished product include those for:

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

Do not store above 25°C.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

This application was for a generic ‘hybrid’ application in accordance with Article 13(3) of Directive 2001/82/EC, as amended. Therefore, the submission of pharmacological and toxicological data are not required.

User Safety

A user risk assessment was provided in compliance with the relevant guideline. The product is the same pharmaceutical form, contains the same active

substance in the same quantity, and the same excipients in similar quantities as the reference product and is therefore expected to have a similar safety profile.

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:

- Wash hands after use.
- Penicillin and cefalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross-sensitivity to cefalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
- Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure such as a skin rash you should seek medical advice and show the Doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
- The cleaning towels supplied with this product contain isopropyl alcohol, which may cause skin or eye irritation in some people. It is recommended to wear protective gloves when administering the product and handling the cleaning towels.

Environmental Safety

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

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

The product is not expected to pose a risk for the environment when used as recommended.

III.B.2 Residues documentation

Residue Studies

No residue depletion studies were conducted because the product is qualitatively and quantitatively the same as the reference product in terms of the active substance, and qualitatively the same in terms of the excipients which is accepted.

MRLs

Cefalonium is listed in Table 1 of Regulation 37/2010 with no MRL required

Withdrawal Periods

The same withdrawal periods as authorised for the reference product have been proposed and are considered sufficient to ensure the safety of the consumer.

Based on the data provided, a withdrawal period of 21 days for meat, 96 hours for milk after calving if the dry period is longer than 54 days, and 58 days for milk following treatment if the dry period is less than or equal to 54 days.

IV CLINICAL DOCUMENTATION

This was an application for a generic 'hybrid' application in accordance with Article 13(3) of Directive 2001/82/EC, as amended. The applicant conducted several *in vitro* tests, demonstrating sufficient similarity between the test and the reference products Therefore, the absence pre-clinical and clinical data is acceptable.

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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