MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

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

FATROSEAL 2.6 g intramammary suspension for dry cows

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

Product name: FATROSEAL 2.6 g intramammary suspension for dry cows	Application number: <ES/V/nnnn/sss/MR or DC>
Applicant: LABORATORIOS SUPPORT PHARMA S.L.	Date: 16/03/2022
Publicly available assessment report	

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0407/001/DC
Name, strength and pharmaceutical form	FATROSEAL 2.6 g intramammary suspension for dry cows
Applicant	LABORATORIOS SUPPORT PHARMA S.L. General Álvarez de Castro, 39 28010 Madrid, Spain
Active substance(s)	Bismuth subnitrate, heavy
ATC Vetcode	QG52X
Target species	Cattle (dairy cows at drying-off).
Indication for use	Prevention of new intramammary infections throughout the dry period. In cows considered likely to be free of sub-clinical mastitis, the product can be used alone in dry cow management and mastitis control.

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.3 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	09/02/2022
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE,CZ, DK, EE, FR, DE, EL, HU, IE, LU, NL, PL, PT, SK, UK(NI)

I. SCIENTIFIC OVERVIEW

For public assessment reports for the first authorisation in a range*:*

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 2.6 g of bismuth subnitrate, heavy as active substance and aluminium stearate, silica colloidal anhydrous and paraffin liquid as excipients.

The container closure system is a single dose LDPE intramammary syringe closed with a LDPE cap containing 4 g of suspension.

The choice of the formulation has been 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.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is Bismuth subnitrate, heavy, an established 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.

Scientific data (ASMF for Bismuth subnitrate heavy) has 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 confirmed.

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 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 (3 years) when stored under the approved conditions (no special storage conditions required).

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a hybrid application according to Article 13 (3), and bioequivalence with a reference product has been demonstrated, results of safety and residues tests are not required.

The safety 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 the consumers.

III.A Safety Testing

Pharmacological Studies

As this is a hybrid application according to Article 13(3), and bioequivalence with a reference product has been demonstrated, results of pharmacological studies are not required.

Toxicological Studies

As this is a hybrid application according to Article 13(3), and bioequivalence with a reference product has been demonstrated, results of toxicological studies are not required.

The safety aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. The hybrid product does not involve any risk to the person who administers the product if it is used in accordance with the conditions established in the summary of the product characteristics. The risk management measures proposed by the applicant are the same as those authorised for 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 because the predicted environmental concentration of the VMP in soil (PECsoil) is below 100 µg/kg. It can be concluded that the use of FATROSEAL results in acceptable risk for the environment.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used in accordance with the SPC.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted on the basis that bioequivalence with the reference product has been demonstrated.

MRLs

Bismuth subnitrate is listed in Table 1 of the annex to Commission Regulation (EU) No 37/2010.

MRLs are listed below:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Bismuth subnitrate	Not applicable	All food producing species	No MRL required	Not applicable	For oral use
		Bovine	No MRL required	Not applicable	For intramammary use only

The excipients are classified as follows:

Excipient	*Status*
Silica colloidal anhydrous	*Included in table 1 of Commission Regulation (EU) No 37/2010 – No MRL required. Food additive E-551.*
Aluminium stearate	*Included in table 1 of Commission Regulation (EU) No 37/2010 – No MRL required.*
Liquid paraffin	*Included in table 1 of Commission Regulation (EU) No 37/2010 – No MRL required.* Mineral hydrocarbons

Withdrawal Periods

The same withdrawal periods than the reference product are proposed for the VMP:

Meat and offal: Zero days
Milk: Zero hours

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IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a hybrid 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