IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Mastiseal 2.6 g Intramammary Suspension for Cattle, Dry Cow

PRODUCT SUMMARY

EU Procedure number	IE/V/0334/001/DC
Name, strength and pharmaceutical form	Mastiseal 2.6 g Intramammary Suspension for Cattle, Dry Cow
Active substance(s)	Bismuth subnitrate, heavy
Applicant	Cross Vetpharm Group Ltd.
Legal basis of application	Artilce 13(1), Generic
Date of completion of the procedure	21/10/2014
Target species	Cows
Indication for use	For the prevention of new intramammary infections throughout the dry period
ATCvet code	QG52X

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the

scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA website.

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 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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A.Qualitative and Quantitative Particulars

The product contains the active substance bismuth subnitrate, heavy (2.6 g per syringe) and the excipients liquid paraffin, aluminium di/tri-stearate and colloidal anhydrous silica. The container/closure system consists of a low density polyethylene intramammary syringe with a smooth, tapered hermetically sealed nozzle.

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 at a licensed manufacturing site.

Process validation data for the manufacturing process has 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 has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

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 has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F.Stability

Stability data on the active substance has 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 has 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

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended. The reference product is Teat Seal Non Antibiotic 2.6 g Intramammary Suspension, Dry Cow (VPA 10960/45/1, MAH: Cross Vetpharm Group Limited).

The formulation and manufacturing of the product is the same as that of the reference product. It is accepted that the product can be considered bioequivalent with the reference product.

III.ASafety Testing

Pharmacological Studies

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, results of pharmacological tests are not required.

Toxicological Studies

As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, results of toxicological tests are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that no special warnings are required.
The precaution as listed on the product literature is adequate to ensure safety to users of the product.

Environmental Risk Assessment

Phase I
The environmental risk assessment can stop in Phase I because the natural substance bismuth in the product will not alter the concentration or distribution of bismuth in the environment.

Conclusion
Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.BResidues Documentation

Residue Studies

No residue depletion studies were conducted because this is a generic application according to Article 13(1) and the formulation and manufacturing of the product is

identical to that of the reference product, Teat Seal Non Antibiotic 2.6 g Intramammary Suspension, Dry Cow.

MRLs

Bismuth subnitrate is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	**Marker residue**	**Animal species**	**MRL**	**Target Tissues**
Bismuth subnitrate	NOT APPLICABLE	All food producing species	No MRL required	For oral use only.
		Bovines	No MRL required	For intramammary use only.

Withdrawal Periods

Given that the product is considered to be identical to the reference product, it is accepted that authorised withdrawal periods for the reference product can be applied to the product.

A withdrawal period of zero days for meat in dairy cattle and zero hours for milk are justified.

III. SAFETY ASSESSMENT

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 HPRA website.

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.

Changes:
None.

IV. CLINICAL ASSESSMENT

This is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended. The reference product is Teat Seal Non Antibiotic 2.6 g Intramammary Suspension, Dry Cow (VPA 10960/045/001, MAH: Cross Vetpharm Group Limited).

The formulation and manufacturing of the product is the same as that of the reference product. It is accepted that the product can be considered identical to the reference product. The omission of bioequivalence studies and the absence of pre-clinical/clinical studies are justified.

IV.APre-Clinical Studies

Tolerance in the Target Species of Animals

Product specific target animal safety data have not been presented. Given that the product is considered identical to the reference product, and thus bioequivalent, it is accepted that the safety profile of both products will be similar. Therefore, the text agreed for sections 4.6 and 4.10 of the authorised reference product can be applied to the test product.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

Efficacy data have not been presented. As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been accepted, 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 benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 HPRA website.

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.

Changes:
None.