College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A HOMEOPATHIC VETERINARY MEDICINAL PRODUCT

Mammicurine 880 injector voor intramammair gebruik

Created: September 2020

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Mammicurine 880 injector voor intramammair gebruik Injector for intramammary use
Applicant	VEE SERVICE IDAC Thomas Edisonweg 36 5151 DJ Drunen
Active substance(s)	Calendula officinales 1 DH 0.25 ml Echinacea angustifolia 4 CH 0.04 ml Phytolacca decandra 2 DH 0.25 ml
Target species	Cattle, sheep, goat
Indication for use	Traditional homeopathic veterinary medicinal product to support a restored udder functioning in cattle, sheep and goat.

MODULE 2

The Summary of Product Characteristics for this homeopathic product is available on the Diergeneesmiddeleninformatiebank.

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. Based on article 19 of Directive 2001/82/EC Homeopathic veterinary medicinal products other than those referred to in Article 17(1) shall be authorised in accordance with Articles 12, 13a, 13b, 13c, 13d and 14.
Date of authorisation	6 October 2020

I. SCIENTIFIC OVERVIEW

Mammicurine 880 injector for intramammary use is a generic application according to Article 13(1) of Directive 2001/82/EC as amended. The reference product is BONAMAM INTRAMAMMAIRE. Authorisation numbers:679269 2 and 679270 0 . Authorised since 1 March 2006 in France.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

10 g of this homoeopathic medicinal product contains the active substances Calendula officinalis 2CH 0.25 ml, Echinacea angustifolia 4CH 0.04 ml, Phytolacca decandra 2CH 0.25 ml and the excipients ethanol 96% (V/V), carbomers (Carbopol 974 PNF), triethanolamine and water for injections.

The container/closure system consists of a 12 ml injector, composed of a 12 ml barrel (low density polyethylene) + plunger (low density polyethylene)

The absence of preservatives is 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 at 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 substances are Calendula officinalis 2CH, Echinacea angustifolia 4CH and Phytolacca decandra 2CH.The respective raw materials Calendula officinalis, Echinacea

angustifolia and Phytolacca decandra are established homoeopathic substances described in the French Pharmacopoeia (Ph. Fr.).

The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substances specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

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 (pharmaceuticals)

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

The active substances are fully tested to ensure compliance with their specification immediately prior to their use in manufacture of the product.

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

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13, and the product is identical to the reference product, results of pharmaco-toxicological tests are not required.

The pharmaco-toxicological 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 and consumers.

User Safety

As this is a generic application according to Article 13, and the product is identical to the reference product, studies on the safety of users are not required.

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.

Environmental Risk Assessment

For a generic application a separate Environmental Risk Assessment is required.

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 active substances are highly diluted natural substances, the use of the highly diluted substances will not alter the concentration or distribution of the substance in the environment.

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 the environment.

MRL and withdrawal periods

As this is a generic application according to Article 13, and the product is identical to the reference product residue studies are not required. The withdrawal periods for this product are equivalent to those of the reference product. A withdrawal period of zero days can be granted for all target species.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A & IV.B Pre-Clinical and Clinical Studies

As this is a generic application according to Article 13, and the product is identical to the reference product, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product, which is 'Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of homoeopathic medicine.'

Tolerance in the Target Species

As the composition of the product is identical to the reference product, no data on the tolerance in the target species is required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure the tolerance in the target species.

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 quality and safety of the product for the target species, humans and the environment is acceptable.