College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A HOMEOPATHIC VETERINARY MEDICINAL PRODUCT

Nageboorte Pil

Created: February 2020

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Nageboorte pil, tablet for intrauterine use
Applicant	Feed Farm B.V. Bommelsekade 7 5301 KL Zaltbommel
Active substance(s)	Arnica 30K 25 mg Bellis perennis 30K 25 mg Caulophyllum 30K 25 mg Sabina 30K 25 mg
Target species	Cattle, sheep
Indication for use	Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of homoeopathic medicine.

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

I. SCIENTIFIC OVERVIEW

The applicant has submitted data which demonstrate that the product can be safely used in cattle and sheep. In addition the applicant has demonstrated that 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 Summary of Product Characteristics.

As an application was made as 'Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of homoeopathic medicine.' assessment of the efficacy was not part of the assessment procedure. Therefore no indication is mentioned in the Summary of Product Characteristics.

In conclusion 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 cattle, humans and the environment is acceptable.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

This homoeopathic medicinal product contains 25 mg of each of the active substances Arnica 30K, Bellis perennis 30K,Caulophyllum 30K and Sabina 30K per intrauterine tablet. Excipients are lactose monohydrate, sodium starch glycolate, microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate and Ponceau 4R colorant E124.

The container/closure system consists of a thermoformed and sealed blister made of white PVC/PE/PVDC and aluminium. Each blister contains five intrauterine tablets. The blisters are packed per 2 in a carton box.

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 Arnica 30K, Bellis perennis 30K,Caulophyllum 30K and Sabina 30K. The respective raw materials Arnica montana (whole plant), Bellis perennis, Caulophyllum thalictroides and Juniperus sabina are established homoeopathic substances described in the French Pharmacopoeia (Ph. Fr.) or the German Homoeopathic Pharmacopoeia (GHP).
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.

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> (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

Stability data on most of the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions. Where stability data are lacking, the active substance is fully tested to ensure compliance with its specification immediately prior to its 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

III.A Safety Testing

User Safety

Information has been provided which made plausible that the 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 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.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because all ingredients are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

MRLs

Active substances:

Arnica 30K

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Bellis perennis 30K

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Caulophyllum 30K

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Sabina 30K

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Withdrawal Periods

Since there are no MRLs required for the active substances or excipients of Nageboorte pil, a withdrawal period of zero days for Nageboorte pil is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As an application was made as 'Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of homoeopathic medicine.' assessment of the efficacy was not part of the assessment procedure. Therefore no indication is mentioned in the Summary of Product Characteristics.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

Information has been provided which made plausible that the tolerance in cattle and sheep is acceptable.

IV.B Clinical Studies

No clinical studies have been conducted.

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.