College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A HOMEOPATHIC VETERINARY MEDICINAL PRODUCT

Traumeel S ad us. vet.

Created: April 2020

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Traumeel S ad us. vet, solution for injection	
Applicant	Heel Belgium nv Booiebos 25 9031 Drongen (Gent) België	
Active substance(s)	Arnica montana D4 Belladonna D4 Calendula officinalis D4 Chamomilla D5 Hepar sulphur D6 Millefolium D5 Symphytum officinale D8 Aconitum napellus D4 Bellis perennis D4 Mercurius solubilis D8 Hypericum perforatum D4 Echinacea D4 Echinacea purpurea e planta tota D4 Hamamelis virginiana D4	0,5 g 0,5 g 0,5 g 0,5 g 0,5 g 0,5 g 0,5 g 0,3 g 0,25 g 0,25 g 0,15 g 0,125g 0,125g 0,05 g
Target species	Horses, Cattle, Pigs, Sheep, Goats	
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	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

Traumeel S ad. us. vet. is a generic application according to Article 13(1) of Directive 2001/82/EC as amended. The reference product is Traumeel S ad us. vet.. Authorisation number: ZNR 400338.00.00. Authorised since 17 January 2002 in Germany.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

1 ampoule of 5 ml (=5.0 g) of this homoeopathic medicinal product contains the following active substances:

Arnica montana	D4	0,5 g
Belladonna	D4	0,5 g
Calendula officinalis	D4	0,5 g
Chamomilla	D5	0,5 g
Hepar sulphur	D6	0,5 g
Millefolium	D5	0,5 g
Symphytum officinale	D8	0,5 g
Aconitum napellus	D4	0,3 g
Bellis perennis	D4	0,25 g
Mercurius solubilis	D8	0,25 g
Hypericum perforatum	D4	0,15 g
Echinacea	D4	0,125 g
Echinacea purpurea e planta tota	D4	0,125 g
Hamamelis virginiana	D4	0,05 g

Excipients are water for injections and sodium chloride.

The container/closure system consists of colourless OPC glass hydrolytic type I (Ph. Eur. 3.2.1) ampoules of 1 ml, 2 ml or 5 ml.

The absence of specific 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 Arnica montana D4, Belladonna D4, Calendula officinalis D4, Chamomilla D5, Hepar sulphur D6, Millefolium D5, Symphytum officinale D8, Aconitum napellus D4, Bellis perennis D4, Mercurius solubilis D8, Hypericum perforatum D4, Echinacea D4, Echinacea purpurea e planta tota D4 and Hamamelis virginiana D4. The respective raw materials Arnica montana, Atropa bella-donna, Calendula officinalis, Chamomilla recutita, Hepar sulfuris, Achillea millefolium, Symphytum officinale, Aconitum napellus, Bellis perennis, Mercurius solubilis Hahnemanni, Hypericum, Echinacea, Echinacea purpurea ex planta tota and Hamamelis virginiana are established homoeopathic substances described in the European Pharmacopoeia (Ph. Eur.) or the German Homoeopatic 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 the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances 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

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 of Animals

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.