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College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

**Graadt van Roggenweg 500
3531 AH Utrecht
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NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A
HOMEOPATHIC VETERINARY MEDICINAL PRODUCT**

**Traumeel S gel
Created: June 2020**

Product name Traumeel S gel	REG NL H 114807
Applicant Heel Belgium nv	Publicly available assessment report

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Traumeel S gel, solution for injection	
Applicant	Heel Belgium nv Booiebos 25 9031 Drongen (Gent) België	
Active substance(s)	Arnica montana D3 Belladonna D1 Calendula officinalis Ø Chamomilla Ø Hepar sulphur D6 Millefolium Ø Symphytum officinale D4 Aconitum napellus D1 Bellis perennis Ø Mercurius solubilis D6 Hypericum perforatum D6 Echinacea Ø Echinacea purpurea e planta tota Ø Hamamelis virginiana Ø	1,5 g 0,05 g 0,45 g 0,15 g 0,025 g 0,09 g 0,1 g 0,05 g 0,1 g 0,04 g 0,09 g 0,15 g 0,15 g 0,45 g
Target species	Horses, Cattle, Pigs, Sheep, Goats, Dogs, Cats	
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](#).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application according to 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 gel vet is a generic application according to Article 13(1) of Directive 2001/82/EC as amended. The reference product is Traumeel Gel ad us. vet.. Authorisation number: Reg. Nr. 400858.00.00. Authorised since 10.03.2006 in Germany.

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 the target species, humans and the environment is acceptable.

II. QUALITY ASPECTS

A. *Qualitative and quantitative particulars*

100 g of this homeopathic medicinal product contains the following active substances:

Arnica montana	D3	1,5 g
Belladonna	D1	0,05 g
Calendula officinalis	Ø	0,45 g
Chamomilla	Ø	0,15 g
Hepar sulphur	D6	0,025 g
Millefolium	Ø	0,09 g
Symphytum officinale	D4	0,1 g
Aconitum napellus	D1	0,05 g
Bellis perennis	Ø	0,1 g
Mercurius solubilis	D6	0,04 g
Hypericum perforatum	D6	0,09 g
Echinacea	Ø	0,15 g
Echinacea purpurea e planta tota	Ø	0,15 g
Hamamelis virginiana	Ø	0,45 g

Excipients used are carbomers (980), sodium hydroxide, purified water and ethanol ethanol 96% (V/V).

The container/closure systems consists of

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- Aluminium tubes (50 and 100 g). The protective inside lacquer consists of epoxit-phenolic resin, the lacquer outside is made of polyester resin. The screw cap consists of polypropylene, the thread ring of high-density polyethylene.
- or
- Polyethylene (high-density) squeeze bottles of 250 ml with polypropylene cap.

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 licensed manufacturing sites.

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 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.

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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 sites 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

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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.