**College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board**

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**NATIONAL PROCEDURE**

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A HOMEOPATHIC VETERINARY MEDICINAL PRODUCT

**Pyrogenium compositum**

**Created: December 2019**

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| Name, strength and pharmaceutical form | Pyrogenium compositum, solution for injection |
| Applicant | SaluVet GmbH<br>Stahlstraße 5,<br>88339 Bad Waldsee<br>Germany |
| Active substance(s) | Pyrogenium Dil. D 15<br>Lachesis mutus Dil. D 8<br>Argentum metallicum Dil. D 30 |
| Target species | Cattle, horses, pigs, sheep, goats |
| Indication for use | Cattle:<br>The indications are derived from veterinary homoeopathy remedy pictures. These include:<br>Diseases with fever, reduced general wellbeing due to localised inflammation such as udder inflammation, inflammation of the uterus, claw inflammation, respiratory infections.<br><br>Horses, pigs, sheep and goats:<br>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

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|---|---|
| Legal basis of original application | Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.<br>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

Pyrogenium compositum is a hybrid application according to Article 13(3) of Directive 2001/82/EC as amended. The reference product for the target species cattle is Pyrogenium compositum inject. Authorisation number: ZNR 6857628.00.00. Authorised since 3 April 2012 in Germany. The reference product pyrogenium compositum inject is part of the same global marketing authorisation as Pyrogenium compositum, authorisation number Z.Nr.: 8-30027, as authorised in Austria since 17 February 1998. Therefore a generic application can be applied for.

In addition to the target species cattle which is the generic part of the dossier, the applicant has submitted data which demonstrate that the product can be safely used in the additional target species. 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 SPC.

The efficacy of the product was not demonstrated for the additional target species. Therefore no indication has been granted.

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*

This homoeopathic medicinal product contains the active substances Pyrogenium D15, Lachesis D8, Argentum Metallicum D30 (all 3,30 g per 10 g (=10.2 ml) and the excipients sodium chloride isotonic solution and ethanol 20% m/m.

The container/closure system consists of a 100 ml brown vial for injection (glass type I, Ph. Eur.), with a bromobutyl rubber stopper, 20 mm with aluminium crimp cap and polypropylene top cap.

The product contains 18.9 – 20.9 % (m/m) ethanol. The absence of further 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 Pyrogenium D15, Lachesis D8 and Argentum Metallicum D30. The respective starting materials Pyrogenium nosode, Lachesis mutus and Argentum Metallicum are established homoeopathic substances described in 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*

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

### *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*

According to Article 17 of Directive 2001/82/EC a sufficient degree of dilution guarantees the safety of the medicinal production – In particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture. This is the case for all active substances of Pyrogenium compositum.

As the active substances in Pyrogenium compositum are diluted to less than one part per 10,000 no MRL is required according to Regulation 37/2010.

#### *Excipients:*

According to MRL regulation 37/2010 for ethanol for use as excipient no MRL is required. For sodium chloride no MRL is required.

### *Withdrawal Periods*

Since there are no MRLs required for the active substances and excipients of Pyrogenium compositum, a withdrawal period of zero days for Pyrogenium compositum is justified.

## IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a hybrid application according to Article 13(3), and bioequivalence with a reference product has been demonstrated, efficacy studies are not required for the target species cattle. The efficacy claims for the target species cattle are equivalent to those of the reference product. For the additional target species no efficacy studies have been conducted and therefore no indication has been granted for these additional target species.

### *IV.A Pre-Clinical Studies*

### *Tolerance in the Target Species of Animals*

Information has been provided which made plausible that the tolerance in the target species 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.