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

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**NATIONAL PROCEDURE**

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A HOMEOPATHIC VETERINARY MEDICINAL PRODUCT

**Immulon oraal**

**Created: December 2019**

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| Name, strength and pharmaceutical form | Immulon Oraal, oral solution |
| Applicant | SaluVet GmbH<br>Stahlstraße 5,<br>88339 Bad Waldsee<br>Germany |
| Active substance(s) | Echinacea angustifolia Dil. D 2<br>Lachesis Dil. D 8<br>Phosphorus Dil. D 6<br>Decoctum from Coffea arabica tosta |
| Target species | Cattle, horses, pigs, sheep, goats |
| Indication for use | Cattle (calves):<br>According to anthroposophical knowledge of nature:<br>To harmonise the metabolic and sensory system in newborn calves, e.g. in disease processes involving fever and inflammation (diarrhoea, respiratory disorders).<br><br>Cattle (not calves), horses, pigs, sheep, goats:<br>Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of anthroposophical 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

Immulon oraal is a hybrid application according to Article 13(3) of Directive 2001/82/EC as amended. The reference product for the target species calf is Immulon Dr. Schaette. Authorisation number: ZNR 400021.00.00. Authorised since 5 October 1998 in Germany.

In addition to the target species calf 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*

100 g of this homoeopathic medicinal product contain the active substances Echinacea angustifolia D2 15.0 g, Lachesis D8 20.0 g, Phosphorus D6 15.0 g and Decoctum Coffea tosta 30% 50.0g without excipients.

The container/closure system consists of a 100 ml brown glass bottle, glass type III (Ph. Eur.) with a low density polyethylene syringe insert Luer fitting, a polypropylene screw cap and a polypropylene and high density polyethylene Luer syringe in size 10 ml (dosing aid).

The product contains 35 - 40% (V/V) 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.

The product is manufactured using conventional manufacturing techniques, in accordance with the European Pharmacopoeia and relevant European guidelines.

## C. Control of Starting Materials

The active substances are Echinacea angustifolia D2, Lachesis D8, Phosphorus D6 and Decoctum Coffea tosta 30%. The respective raw materials Echinacea angustifolia, Lachesis mutus, Phosphorus and Coffea Arabica 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

Stability data on 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.

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*

**Echinacea angustifolia Dil. D2**

According to the Summary Report for Echinacea by the Committee for Veterinary Medicinal Products (EMEA/MRL/687/99-FINAL), there is no need to establish an MRL for Echinacea for use in veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per ten. The Committee concluded that in those concentrations the products can be considered as not giving rise to any specific consumer health concerns and provide a sufficient margin of safety.

Echinacea is therefore included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

**Lachesis mutus D8**

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.

Lachesis mutus D8 contains one part per 100 000 000 and can therefore considered to be safe for the consumer.

**Phosphorus D6**

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.

Phosphorus D6 contains one part per 1 000 000 and can therefore considered to be safe for the consumer.

**Decoctum from Coffea arabica tosta**

Coffea arabica is listed as normal foodstuff considered as not falling within the scope of Regulation (EC) No 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (EMA/CVMP/519714/2009–Rev.16; 13 June 2013)

It is therefore concluded that for the Decoctum from Coffea arabica tosta with the main active substance caffeine, there is no maximum residue limit (MRL) according to Commission Regulation (EU) No 37/2010 required.

### *Excipients*

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

### *Withdrawal Periods*

Since there are no MRLs required for the active substances and excipients of Immulon Oraal, a withdrawal period of zero days for Immulon Oraal 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 calf. The efficacy claims for the target species calf 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.