College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Solacyl 1000 mg/g, powder for oral solution for cattle and pigs

Created: November 2021

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0117/001/DC
Name, strength and pharmaceutical form	Solacyl 1000 mg/g, powder for oral solution for cattle and pigs
Applicant	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel The Netherlands.
Active substance(s)	Sodium salicylate (1000 mg/g)
ATC Vetcode	QN02BA04
Target species	Cattle (Calves) and Pigs
Indication for use	Calves : supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g. anti-infective) therapy if necessary Pigs: For the treatment of inflammation in combination with concurrent antibiotic therapy.

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

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.
Date of completion of the original decentralised procedure	27th November 2007
Date product first authorised in the Reference Member State (MRP only)	NA
Concerned Member States for original procedure	Austria, Belgium, Czech Republic, Germany, Denmark, Spain, France, Hungary, Ireland, Italy, Lithuania, Poland, United Kingdom

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
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 demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains Sodium salicylate 1000 mg/g (quantitative).

The container/closure system contains sachets/bags consisting of the following materials: on the outside a white layer, inside different transparent layers, a sub-layer of aluminium and an inner layer of polyethylene. Pack sizes are 100 g, 250 g, 500 g, 1.0 kg, 25 kg and 5.0 kg.

Sachets/bags consisting of the following materials: on the outside a plastic layer, inside layers of polyethylene and aluminium and an inner layer of ionomer. Pack sizes are 100 g, 250 g, 1.0 kg, 2.5 kg and 5.0 kg.

Sachets/bags consisting of the following materials: on the outside a plastic layer, inside layers of polyethylene and aluminium and an inner layer of polyethylene. Pack sizes are 100 g, 250 g, 1.0 kg, 2.5 kg and 5.0 kg.

The choice of the formulation is justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

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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 in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is Sodium salicylate 1000 mg/g, an established active substance described in the European Veterinary Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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 substance 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

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 6 months

Shelf-life after reconstitution in drinking water according to directions: 24 hours.

Shelf-life after reconstitution in milk(replacer) according to directions: 6 hours

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III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological tests are not required.

The pharmacological and toxicological aspects of this product are identical to the reference product.

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological tests are not required.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological tests are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that direct skin contact and aspiration should be avoided during application. Therefore it is recommended to wear gloves and a dust mask.

Because of the risk of eye irritation, contact with the eyes should be avoided. In the event of eye contact, the user is advised to flush the eye with copious amounts of water for 15 minutes, and seek medical advice if irritation persists.

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.

Phase I:

Based on biodegradation data, there is sufficient evidence that salicyclic acid will degrade rapidly and completely in manure of the target animals and that therefore the assessment may end in phase I. Consequently, no phase II assessment is deemed necessary, even though the Phase I assessment showed that the initial predicted environmental concentration in soil (PECsoil initial see table) is greater to 100 µg/kg.

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Target animal	PEC soil µg/kg
calf	**296**
Weaner pig	**131**
Fattening pig	89
Sow & litters	32

III.B Residues documentation

Residue Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

Withdrawal Periods

Based on the data provided above, a withdrawal period of 0days for meat in calves and pigs are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Vetrinary Medicines Agencies website (www.HMA.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Summary of change	**Section updated**	**Approval Date**
Changes according to the decision of the European Committee as consequence of a Class Referral on Sodium Salicylate. (NL/V/0117/001)	NA	28th October 2008
Renewal – NL as RMS (NL/V/0117/001/R/001)	NA	24th October 2012
Change in immediate package of the finished product concerning the qualitative and quantitative composition. (NL/V/0117/001/IA/001)	Module 3 II.A	16th August 2012
Change in the QPPV and the contact details of the QPPV. (NL/V/xxxx/IA/006/G)	NA	6th March 2013
Deletion of manufacturing sites. (NL/V/0117/001/IA/003)	NA	18th April 2013
Change in immediate package of the finished product concerning the qualitative and quantitative composition and update of the in process control specification. (NL/V/0117/IB/004/G)	Module 3 II.A	9th February 2017
Update of the dossier concerning the active substance. (NL/V/0117/001/II/005)	NA	27th August 2018
Repeat Use – NL as RMS, addition of CMSs: LU, PT, EE, SK, SI, HR. (NL/V/0117/001/E/001)	NA	6th February 2019

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Change in the QPPV and/or QPPV contact details and/or back-up procedure. (NL/V/xxxx/IA/033/G)	NA	11th January 2019