Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Pronestesic 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (AT, BE, CY, CZ, DE, DK, EE, EL, ES, HR, IE, IT, LT, LU, LV, NL, PL, PT, SI, SK, UK)
Pronestesic vet 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (FI, IS, SE)
Malleva vet 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (NO)
Pronestesic 34.65 mg/ml / 0.02 mg/ml solution for injection for horses, cattle, pigs and sheep (FR)

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0238/001/DC
Name, strength and pharmaceutical form	Pronestesic 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (AT, BE, CY, CZ, DE, DK, EE, EL, ES, HR, IE, IT, LT, LU, LV, NL, PL, PT, SI, SK, UK) Pronestesic vet 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (FI, IS, SE) Malleva vet 40 mg/ml / 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep (NO) Pronestesic 34.65 mg/ml / 0.02 mg/ml solution for injection for horses, cattle, pigs and sheep (FR)
Applicant	SUPPORT PHARMA, S.L. General Alvarez de Castro, 39 28010 Madrid, Spain
Active substance(s)	Procaine hydrochloride Epinephrine tartrate
ATC Vet code	QN01BA52
Target species	Horses, cattle, pigs and sheep.
Indication for use	Local anaesthesia with a long-lasting anaesthetic effect. Horses, cattle, pigs and sheep: infiltration anaesthesia and perineural anaesthesia (see section 4.5.).

MODULE 2

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

MINISTERIO DE SANIDAD,
SERVICIOS SOCIALES
E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13.1 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	D210: 24/02/2016
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, HR, CY, CZ, DK, EE, FI, FR, DE, EL, IS, IE, IT, LV, LT, LU, NL, NO, PL, PT, SK, SI, SE, UK

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. Composition

The product contains 40 mg/ml procaine hydrochloride and 0.036 mg/ml epinephrine tartrate and excipients (sodium metabisulfite, sodium parahydroxybenzoate and disodium edetate)

The container/closure system is a type II amber glass vials, closed with a chlorobutyl siliconised rubber stopper type I and a flip-off aluminium collar, in a cardboard box. The particulars of the containers and controls performed are provided and conform to the regulation.

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 from 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 procaine hydrochloride and epinephrine tartrate, established active substances described in the European Pharmacopoeia. 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

Not applicable

F. 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.

G. 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.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

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

The safety and residue aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are similar to those of the reference product and are adequate to ensure safety of the product to users, the environment, and the consumers.

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, the results of pharmacological studies are not required.

Toxicological Studies

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

User Safety

The applicant has not provided a user risk assessment. Pronestesic 40 mg/ml solution for injection for horses, cattle, pigs and sheep will be used in the same species, at the same doses and treatment regimen, and has the same qualitative and quantitative composition as the reference product. For these reasons, the risk for the user can be considered identical for both products.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that the ERA can stop in question 5 of Phase I, since the product will be used only for treatment of a small number of animals.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

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, no residue depletion studies are required.

MRLs

Procaine hydrochloride and epinephrine tartrate are both listed in Annex I of Commission Regulation Nº 37/2010, with a no MRL required status for all food producing species.

Withdrawal Periods

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the same withdrawal periods are justified:

- Horse, cattle and sheep:
    - Meat and offal: zero days
    - Milk: zero days
- Pig: Meat and offal: zero days

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 veterinary Heads of 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.

None