Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Procanest 40 mg/ml + 0.036 mg/ml Solution for Injection for Sheep

Date Created: **March 2022**

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Procanest 40 mg/ml + 0.036 mg/ml Solution for Injection for Sheep, Solution for injection
Applicant	Richter Pharma AG, Feldgasse 19, Wels, 4600, Austria
Active substance	Procaine Hydrochloride Adrenaline Tartrate
ATC Vetcode	QN01BA52
Target species	Sheep
Indication for use	Local anaesthesia with an anaesthetic effect of 1 – 2 hours. • Infiltration anaesthesia • Perineural anaesthesia

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	A generic product application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	29/12/2021

I. SCIENTIFIC OVERVIEW

This is a National generic application for Procanest (Procaine-Adrenaline – solution for Injection) containing 40.0 mg/ml procaine hydrochloride and 0.036 mg/ml adrenaline tartrate.
This application was submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC. The reference product is Procaine Hydrochloride 4 % + Adrenaline – VMD, marketed by VMD.nv, which has been authorised in Belgium since September 1974. The applicant claimed exemption from the requirement for bioequivalence studies in accordance with exemption 7.1.b) of the Guideline on the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMA/CVMP/016/2000-Rev.3-corr).
Exemption from conducting studies was accepted, target animal safety and efficacy may be extrapolated from the reference product, and the omission of pharmacological, toxicological and clinical data was acceptable.

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, any reactions observed are indicated in the SPC.[1] 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 [2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The product contains Procaine hydrochloride 40 mg (equivalent to 34.65 mg procaine), Adrenaline acid tartrate / Epinephrine acid tartrate 0.036 mg (equivalent to 0.02 mg adrenaline / epinephrine) and the excipients sodium methyl parahydroxybenzoate (E219) and sodium metabisulfite (E223).

The container/closure system consists of amber glass vials closed with a rubber stopper and aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are justified.

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

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation

II.C. Control of Starting Materials

The active substance is adrenaline tartrate an established active substance described in the European 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.

The active substance is procaine hydrochloride an established active substance described in the European 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.

All excipients are described in Ph. Eur. current edition of the European Pharmacopoeia. Suitable specifications were provided for the packaging materials.

II.C.4. Substances of Biological Origin

The applicant provided confirmation that all starting materials and the manufacture of the veterinary medicinal product are incompliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products. Declarations for each starting material and the finished product were provided.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable

II.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.

II.F. Stability

Stability data on the active substance (procaine hydrochloride) 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 active substance (adrenaline tartrate) 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: 2 years
Shelf life after first opening the immediate packaging: 28 days

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

As this is a generic application no data were required.

Toxicological Studies

As this is a generic application no data were required.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.. It identified the main route of exposure is skin contact from handling the product with other exposures being accidental self-injection, eye contact and ingestion.

Due to the product being prescription only and nature of the of the product, it will only be handled, prepared, and administered by professional users (e.g. veterinarians) in the workplace. It is not anticipated that the product will be stored in the home or administered by non-professional users; therefore, the risk of children being accidentally exposed to the product is negligible.
Splashing onto the skin, eyes or oral mucosa is possible should the needle come away from the syringe prior to or during administration; however, given the user profile (i.e. professional users only) this is considered highly unlikely. Accidental self-injection is also possible while handling the syringe containing the solution in preparation for or during administration but, similarly, is unlikely. Ingestion of the product by the user is considered to be highly unlikely.

It is filled in a glass vial sealed with a rubber stopper, preventing accidental exposure during storage or handling of the vials.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:,

- People with known hypersensitivity to adrenaline, procaine or other local anaesthetics of the ester group as well as derivatives of p-aminobenzoic acid and sulphonamides should avoid contact with the product.
- This product may be irritant to the skin, eyes and oral mucosa. Avoid contact with the skin, eyes and oral mucosa. Wash any splashes immediately with plenty of water. Seek medical advice if irritation persists.
- Accidental self-injection may result in cardiorespiratory and/or CNS effects. Care should be taken to avoid accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive.
- Wash hands after use.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The product will be used to treat a small number of animals in a flock or herd and as such environmental exposure will be low. A Phase II ERA was not required.

III.B.2 Residues documentation

Residue Studies

The applicant has not submitted residues data on the basis that the generic product is bioequivalent to the reference product.

Withdrawal Periods

Based on the data provided, a withdrawal period of zero days for meat in sheep and zero hours for milk are justified.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

As this is a generic application no data were required.

Tolerance in the Target Species

Tolerance studies were not required because bioequivalence with the reference product has been established.

Resistance

No resistance studies were required based on the nature of the application.

IV.II. Clinical Documentation

No clinical studies were required based on the nature of the application.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the product is favourable.

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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