Bundesamt für Sicherheit
im Gesundheitswesen

BASG - Federal Office for Safety in Health Care
AGES - Austrian Agency for Health and Food Safety

Traisengasse 5, A-1200 Vienna
www.basg.gv.at

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection

Date: 27/06/2019

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

Modules 1-3 reflect the scientific discussion for the approval of Procamidor Duo 40 mg/ml + 0,036 mg/ml Injektionslösung für Tiere. The procedure was finalised on 05.06.2019. For information on changes after this date please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU procedure number	AT/V/0018/001/DC
Name, strength and pharmaceutical form	Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection (AT, BE, BG, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK) Procamidor Comp Vet 40 mg/ml + 0.036 mg/ml solution for injection (FI, DK, IS, NO, SE)
Applicant	Richter Pharma AG Feldgasse 19 4600 Wels Austria
Active substances	Procaine hydrochloride, Epinephrine bitartrate
ATCvet code	QN01BA52
Target species	Horses, cattle, pigs and 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 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.
Reference medicinal product	Procaine Hydrochloride 4% + Adrenaline - VMD, V.M.D.s.a.
Date of completion of the original decentralised procedure	05.06.2019
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LV, NL, NO, PL, PT, RO, SE, SI, SK, UK

I. SCIENTIFIC OVERVIEW

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep was a decentralised application in accordance with Article 13(1) of Directive No 2001/82/EC as amended (a generic application) with AT as Reference Member State (RMS) and was authorised on 05th June 2019.

Concerned member states were BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LV, NL, NO, PL, PT, RO, SE, SI, SK and UK.

The reference product was first authorised in Belgium on 24th September 1974 on the basis of a full application.

The indication is for local anaesthesia with a long-lasting anaesthetic effect (1 – 2 hours), the product is administered subcutaneous and perineural.

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:

40 mg/ml procaine hydrochloride and 0.036 mg/ml adrenaline tartrate and the excipients sodium methyl parahydroxybenzoate, sodium metabisulfite, disodium edetate, sodium chloride, hydrochloric acid (for pH adjustment) and water for injections.

The container/closure system consists of amber glass vial type II with coated or uncoated bromobutyl rubber stopper type I and aluminium cap in a cardboard box.

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 in accordance with the European Pharmacopoeia and relevant European guidelines. 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 adrenaline tartrate, established active substances described in the European Pharmacopoeia (Ph. Eur). Both active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substance specifications are considered adequate to control the quality of the material each. Batch analytical data demonstrating compliance with these specifications 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

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.

The claim of stability after broaching is acceptable, for details see section 6.3 of SPC.

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

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Since the application was made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on pharmacodynamics and pharmacokinetics are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

Toxicological Studies

Since the application was made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, this information is not required.

User Safety

Since the application was made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, a detailed user safety is not required.

Nevertheless the applicant provided a satisfactory user risk assessment, identifying the risk to the users of the product and the potential routes of exposure. This showed that the most likely routes of exposure to the product would be via skin and ocular exposure and accidental injection. The risks have been identified and appropriate warnings are included in the SPC and product literature.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. Since the product is intended for individual treatment of horses, cattle, sheep and pigs, the exposure of the environment to the product will therefore be very limited. The disposal advice is in line with that recommended in Volume 6C of the NtA and the test product is not expected to pose a risk for the environment when used as recommended.

III.B Residues documentation

Residue Studies

In accordance with the data requirements of the applicable European bioequivalence guideline, it was demonstrated that the product is a generic product and that the residue depletion profile is the same as for the reference product.

MRLs

Maximum Residue Limits for procaine hydrochloride and adrenaline tartrate are included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Procaine	Not applicable	All food producing animals	No MRL required	Not applicable	No entry
Epinephrine	Not applicable	All food producing animals	No MRL required	Not applicable	No entry

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

Withdrawal Periods

The withdrawal periods for the proposed product are the same as those of the reference product, as follows:

Cattle, sheep and horse:
Meat and offal: Zero days.
Milk: Zero hours.

Pig:
Meat and offal: Zero days.

IV. CLINICAL ASSESSMENT (EFFICACY)

Since the application was made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on efficacy are not required as it has already been presented for the reference product.

IV.A Pre-Clinical Studies

Pharmacology

As this was a generic application according to Article 13 (1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product has been demonstrated, pharmacodynamic and pharmacokinetic studies are not required.

Tolerance in the Target Species of Animals

As this was a generic application according to Article 13 (1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product has been demonstrated, tolerance studies are not required.

IV.B Clinical Studies

Since the application was made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on clinical efficacy are not required.

Laboratory Trials

As this was a generic application according to Article 13 (1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product has been demonstrated, laboratory studies are not required as they have already been presented for the reference product.

Field Trials

As this was a generic application according to Article 13 (1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product has been demonstrated, field studies are not required as they have already been presented for the reference product.

The product is efficacious when used according to the SPC.

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 Veterinary 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.

Significant changes

Summary of change (Application number)	**Approval date**
Not applicable	---