ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection for Cattle

PuAR correct as of 20/02/2019 when RMS was transferred to IE.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0332/001/MR
Name, strength and pharmaceutical form	Adrenacaine Solution for Injection for Cattle
Applicant	Norbrook Laboratories Limited
Active substance(s)	Procaine Hydrochloride Adrenaline (Epinephrine) (as Adrenaline Acid Tartrate)
ATC Vetcode	QN01BA52
Target species	Cattle
Indication for use	The product is indicated for use in minor surgical procedures particularly dehorning and disbudding in cattle.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(1) of Directive 2001/82/EC as amended by Directive 2004/28/EC.
Date of completion of the original mutual recognition procedure	30 June 2009
Date product first authorised in the Reference Member State (MRP only)	07 July 2004
Concerned Member States for original procedure	Ireland

I. SCIENTIFIC OVERVIEW

Adrenacaine Solution for Injection for Cattle contains the active substances procaine hydrochloride and adrenaline (epinephrine) (as adrenaline acid tartrate). The product is authorised to be used in cattle. The product is indicated for use in minor surgical procedures particularly dehorning and disbudding. The product is administered subcutaneously and the dosage rate is 2-5 ml.

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 and 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.

II. QUALITY ASPECTS

A. Composition

The product contains procaine hydrochloride and adrenaline (epinephrine) (as adrenaline acid tartrate) as active substances and chlorocresol, sodium metabisulphate E223, sodium chloride, sodium hydroxide, hydrochloric acid and water for injections as excipients.

The product is packaged in 100 ml amber type I glass vials with bromobutyl bungs and aluminium caps.

The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation is justified.

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 procaine hydrochloride and adrenaline (epinephrine) (as adrenaline acid tartrate) are established active substances and supporting data have been provided. It is considered that the manufacturing process is adequately controlled and the active substance specifications have been suitably justified.

There are six excipients used in the formulation and each has been used previously in veterinary medicines. All excipients have monographs in the Ph. Eur. and each complies with the requirements of the current edition of the Ph. Eur.

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

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided. The specification includes: appearance, pH, identity and assay.

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. The satisfactory validation data for the analytical methods have been provided.

G. Stability

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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

In-use shelf life
Shelf life after opening the immediate packaging: 28 days

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

Pharmacological Studies

Since the application is 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 pharmacodynamics and pharmacokinetics are not required.

Toxicological Studies

Since the application is 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 toxicology are not required.

User Safety

The following operator warnings are included in the SPC and product literature:
Care should be taken to avoid accidental self-injection.
In the event of self-injection, seek medical attention and show the label to the physician. Immediately wash off any splashes to the eyes or skin with copious amounts of water.
Seek medical attention if irritation occurs.
Wash hands after use

Ecotoxicity

The environmental risk assessment was carried out in accordance with VICH Phase I guidelines and using the CVMP guidance in support of VICH guidelines.
The environmental risk assessment demonstrated that use of Adrenacaine Injection would not result in extensive environmental exposure.
Warnings and precautions as listed on the SPC and product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

Since the application is 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 residues are not required.

Withdrawal Periods

The following withdrawal periods are included in the SPC and product literature.
Meat: zero days
Milk: zero hours

IV CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

Since the application is 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, this information is not required as it has already been presented for the reference product.

Pharmacokinetics

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, the applicant is exempted from the conduct of bioequivalence studies in accordance with the CVMP ‘Guidelines for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products’.

Tolerance in the Target Species of Animals

The applicant conducted a target animal safety study in cattle following subcutaneous administration of procaine and adrenaline injection. The study was conducted in accordance with the principles of Good Laboratory Practice. The study concluded that the product is safe to use in cattle under field conditions.

IV.B Clinical Studies

The indications and dose for use of Adrenacaine injection in cattle are essentially the same as those in the SPC for the reference product, therefore the clinical data are not required.

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 benefit-risk 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 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.

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