Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Mepidor 20 mg/ml Solution for Injection (UK, BE, IT)
Mepidor vet. 20 mg/ml Solution for Injection (IS, NO, PT)

PuAR correct as of 23/01/2018 when RMS was transferred to PT. Please contact the RMS for future updates

Date Created: October 2016

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0585/001/DC
Name, strength and pharmaceutical form	Mepidor 20 mg/ml Solution for Injection
Applicant	Richter Pharma AG Feldgasse 19 4600 Wels AUSTRIA
Active substance	Mepivacaine hydrochloride
ATC Vetcode	QN01BB03
Target species	Horses (non-food producing)
Indication for use	Mepivacaine is indicated for infiltration, nerve block, intra-articular and epidural anaesthesia in non-food producing horses.

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 application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	27/07/2016
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Belgium, Iceland, Italy, Norway, Portugal

I. SCIENTIFIC OVERVIEW

This was a generic application submitted in accordance with Article 13 (1) of Directive 2001/82/EC (as amended). The reference product is Intra-Epicaine 2.0% w/v solution for injection authorised in the UK since 1990. The product fulfils the requirements for a waiver from bioequivalence studies in accordance with exemption 7.1.d of the Guideline on the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMA/CVMP/016/00-Rev 2).

Mepidor is indicated for infiltration, nerve block, intra-articular and epidural anaesthesia in non-food producing horses.

The product is administered using aseptic precautions.

For infiltration:	As required but as a guide 2-5 ml.
For nerve block:	2-10 ml depending on location.
For intra-articular anaesthesia:	5 ml.
For epidural anaesthesia:	4-10 ml depending on the depth and extent of anaesthesia required.

In all instances the dosage should be kept to the minimum required to produce the desired effect. The depth and extent of anaesthesia should be determined by pressure with a blunt point, such as the tip of a ball point pen, before commencing manipulations. The duration of action is about 1 hour. It is recommended that the skin should be shaved and thoroughly disinfected prior to the intra-articular or epidural administration.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto 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, 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 QUANTITIATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains mepivacaine hydrochloride 20 mg (equivalent to 17.4 mg mepivacaine) and excipients sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

The container/closure system consists of a clear glass vial with a bromobutyl rubber stopper or bromobutyl stopper with a fluorinated polymer coating 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 absence 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 manufacturing method consists of solubilisation and terminal sterilisation.

Process validation data on the product have been presented in accordance with the relevant European guidelines

II.C. Control of Starting Materials

The active substance is mepivacaine hydrochloride, an established 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. Appropriate CEP data were provided.

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

All excipients are monographed within the European Pharmacopoeia, acceptable Certificates of Analysis were provided. Packaging was suitably verified for use.

II.C.4. Substances of Biological Origin

A statement was provided confirming that all starting materials and manufacture are in compliance with the requirements of the *Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3)*. Separate TSE declarations are provided for each of the excipients.

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 sites have been provided demonstrating compliance with the specification. Control tests on the finished product include: appearance, clarity, pH, density, fill volume, identification and assay of mepivacaine hydrochloride, identification of the excipients and sterility.

II.F. Stability

The active substance is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product. 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. Batches were stored under VICH[3] conditions of 25°C/60% RH and 40°C/75% RH for a variety of time periods, and the results are reflected in the established shelf-life data information provided in the SPC.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

This product does not contain an antimicrobial preservative. Use the vial on one occasion only. Discard any unused material.

Keep the vial in the outer carton in order to protect from light.

[3] VICH – International Cooperation on Harmonisation of Technical requirements for Veterinary Medicinal Products.

This veterinary medicinal product does not require any special temperature storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

For generics, insert in the relevant sections as appropriate:

As this is a generic application according to Article 13 (3) and bioequivalence with a reference product has been established, results of pharmacological and toxicological tests are not required.

Warnings and precautions as listed on the product literature are in line with those of the reference product and are adequate to ensure safety of the product to users and the environment.

III.A Safety Documentation

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that

- People with known hypersensitivity to mepivacaine or other local anaesthetics of the amide group should avoid contact with the veterinary medicinal product.
- This product may be irritating to the skin and eyes.
- Avoid contact with the skin and eyes. Wash any splashes from skin and eyes immediately with plenty of water. Seek medical advice if irritation persists.
- Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the product.
- 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.
- Wash hands after use.

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

Environmental Safety

An environmental risk assessment was carried out in accordance with VICH[4] and CVMP[5] guidelines.

[4] Guideline on Environmental Impact Assessments (EIAS) for Veterinary Medicinal Products – Phase I. CVMP/VICH/592/98-FINAL

Phase I:

The product will only be used in non-food horses and as a result environmental exposure will be low. A Phase II ERA was not required. In addition 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.

Withdrawal Periods

The product is not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

IV CLINICAL DOCUMENTATION

As this is a generic application according to Article 13 (3) and bioequivalence with a reference product has been established 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 benefit/risk profile of the product(s) is favourable.

[5] Revised Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH guidelines GL6 and GL 38. EMEA/CVMP/ERA/418282/2005-Rev.

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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