IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Mepiblock 20 mg/ml solution for injection for horses

PRODUCT SUMMARY

EU Procedure number	IE/V/0375/001/DC
Name, strength and pharmaceutical for	Mepiblock 20 mg/ml solution for injection for horses
Active substance(s)	Mepivacaine hydrochloride
Applicant	Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, Netherlands
Legal basis of application	Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of procedure	18th October 2017
Target species	Horses
Indication for use	Mepivacaine is indicated for intra-articular and epidural anaesthesia in horses.
ATCvet code	QN01BB03
Concerned Member States	AT, BE, DE, DK, ES, FI, FR, IT, NL, NO, PL, PT, SE

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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 benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

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A. Qualitative and Quantitative Particulars

The product contains 20 mg/ml of mepivacaine hydrochloride and the excipients sodium chloride, sodium hydroxide and water for injections.
The container/closure system is 10 ml clear Type I glass vials with red chlorobutyl rubber stoppers and aluminium seals.
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 at a licensed manufacturing site.
Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is mepivacaine 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 has been provided.

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.

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 has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability
Stability data on the active substance has 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 has 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
Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The application for marketing authorisation was submitted in accordance with Article 13(3) (that is a generic hybrid application) of Directive 2001/82/EC, as amended. The reference product chosen by the applicant was Intra-epicaine 20 mg/ml solution for injection, as registered in Ireland (VPA 10799/001/001 – Dechra Limited). Article 13(3) was chosen as the legal basis of the application due to a change in target species from 'non-food producing horses' to 'horses' and deletion of certain indications relative to the reference product.

III.A Safety Testing
Given that bioequivalence between the candidate formulation and the reference product was accepted, pharmacological and toxicological data were not required.

User Safety
The applicant provided a user safety assessment in compliance with the relevant guideline. Mepivacaine was noted to be a potential sensitiser and to cause intradermal irritation, slight eye irritation and intramuscular irritation. In addition, mepivacaine is reported to cross the placenta with the potential for effects on the foetus. It was shown that a potential risk for the user may arise following accidental

dermal, systemic or ocular exposure to the formulation. The SPC includes a number of user safety warnings in order to mitigate against such risks. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted because the MRL status of the active substance mepivacaine is 'no MRL required' and is therefore, generally considered to be safe. In addition, mepivacaine is extensively metabolised and rapidly excreted and is used in a small number of individual animals only, for infrequent and non-regular treatments.

MRLs

Mepivacaine is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as 'No MRL required' For intra-articular and epidural use as local anaesthetic only.

Withdrawal Periods

Based on the information provided above, a withdrawal period of 2 days for meat in horses and 2 days for milk are justified.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

No target animal tolerance studies were conducted. Given that the product is considered to be identical to the reference product, will be administered to the same target species using the same posology and route of administration already approved for the reference product, it was concluded that no difference in tolerance in the target species is to be expected between candidate and reference product formulations. The omission of target animal tolerance data was therefore accepted. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

The application was submitted under Article 13(3) of Directive 2001/82/EC, as amended. An exemption from bioequivalence studies was accepted on the basis that the proposed product is identical to the reference product. As bioequivalence with a reference product has been accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product with the exception that this product is limited to intra-articular and epidural anaesthesia only.

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.

VI. 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 HPRA website.

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.

Changes:
None.