Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
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(Germany)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Domidine

Date: January 2007

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0115/001/MR
Name, strength and pharmaceutical form	Domidine, 10 mg/ml, solution for injection
Applicant	Eurovet Animal Health B.V. Handelsweg 25 5530 AD Bladel The Netherlands
Active substance(s)	Detomidine hydrochlorid
ATC Vetcode	QN05CM90
Target species	Horse, Cattle
Indication for use	For the sedation and slight analgesia of horses and cattle, to facilitate physical examinations and treatments, such as minor surgical interventions. Detomidine can be used for: • Examinations (e.g. endoscopia, rectal and gynaecological examinations, X-rays). • Minor surgical procedures (e.g. treatment of wounds, dental treatment, tendon treatment, excision of skin tumours, teat treatment). • Before treatment and medication (e.g. stomach tube, horse shoeing). For premedication prior to administration of injection- or inhalation anaesthetics.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (www.HEVRA.org).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 of Directive 2001/82/EC as amended.
Date of completion of the original Mutual recognition procedure Decentralised procedure	27 September 2006
Date product first authorised in the Reference Member State (MRP only)	18 April 2006
Concerned Member States for original procedure	Austria; Belgium; Czech Republic; Denmark; Spain; Finland; France; Hungary; Ireland; Italy; Lithuania; Luxemburg; The Netherlands; Poland; Portugal; Sweden; Slovenia; Slovakia; United Kingdom

I. SCIENTIFIC OVERVIEW

Domidine from Eurovet Animal Health B.V., The Netherlands, is a generic product to Domosedan marketed in Germany since 1995 (Reference number 15912.00.00). Domidine is a solution for injection and approved for sedation and slight analgesia of horses and cattle in order to facilitate physical examinations and treatments, such as minor surgical interventions.

Essential similarity of Domidine and the reference product Domosedan was demonstrated according to the relevant EU guidelines. The initial application for Domosedan was assessed before there was a requirement to have a public assessment report; therefore, no details in this section are available.

II. QUALITY ASPECTS

A. Composition

The product contains Detomidine hydrochloride (10 mg /ml), Methyl parahydroxybenzoate, Sodium chloride, Water for injections.

The product is filled into 5, 10 or 20 ml uncoloured glass vials. Teflon-coated halogenated rubber stoppers are secured with aluminium crimp caps. 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.

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.

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

C. Control of Starting Materials

The active substance is Detomidine 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.

An Active Substance Master File (ASMF) has been provided by the manufacturer.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE[1] Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable

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.

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.

G. Stability

Stability studies are presented in the open part of the ASMF. Stability data 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 a 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at 30 °C/65%RH.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

[1] Transmissible Spongiform Encephalopathies

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

Introduction

As this is a generic application according to Article 13 of Directive 2001/82/EC based on the essential similarity of Domidine and the reference product Domosedan, results of pharmacological and toxicological tests are not required.

The applicant has made full reference to the SPC of the reference product Domosedan granted in Germany. However, as this was not completely identical to the SPCs authorised for this product in other concerned member states, efforts have been made during the mutual recognition procedure to produce a harmonised overall accepted product literature for Domidine. Warnings and precautions as listed in the product literature are adequate to ensure safety of Domidine to the user and the environment.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because this is a generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended based on the essential similarity of the reference product Domosedan.

MRLs

Detomidine is listed in Annex II of Council Regulation 2377/90. The marker substance is Detomidine.

Withdrawal Periods

Based on the identical composition and the same parenteral administration between the generic and the reference product a withdrawal period of 2 days for meat and offal and 12 hours for milk of horse and cattle was set.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 of Directive 2001/82/EC based on essential similarity of Domidine and the reference product Domosedan, results of preclinical and clinical studies are not required. The

efficacy claims for Domidine are equivalent to those of the reference product Domosedan.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

When used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the safety of Domidine 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.HEVRA.org).

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.

None