Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

MUTUAL RECOGNITION PROCEDURE
DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cepesedan

Date: 04 June 2007

"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."

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0117/001/MR
Name, strength and pharmaceutical form	Cepesedan, 10 mg/ml, solution for injection
Applicant	CP-Pharma Handelsges. mbH Ostlandring 13 D-31303 Burgdorf, Germany
Active substance(s)	Detomidine hydrochloride
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.

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original Mutual recognition procedure Decentralised procedure	28 February 2007
Date product first authorised in the Reference Member State (MRP only)	21 March 2005
Concerned Member States for original procedure	Austria, Belgium, Czech Republic, Denmark, Spain, Finland, France, Hungary, Ireland, Italy, Lithuania, Latvia, The Netherlands, Norway, Poland, Portugal, Sweden, Slovakia, United Kingdom

I. SCIENTIFIC OVERVIEW

Cepesedan from cp-Pharma GmbH is a generic product to Domosedan which is marketed in Germany since 1995 (reference number 15912.00.00). Cepesedan 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 Cepesedan and the reference product Domosedan was demonstrated according to the relevant EU guidelines. The initial application for Domosendan 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

Active substance:

10 mg / ml Detomidine hydrochloride

Excipients:

Methyl parahydroxybenzoate (E 218)

Sodium chloride

Hydrochloric acid*

Sodium hydroxide*

Water for injection.

* for pH adjustment

The solution is filled in 5 or 20 ml clear glass vial, respectively. The vials are closed with rubber stoppers and sealed with an aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

Since the product is a multidose preparation it must contain a preservative. The choice of Methyl parahydroxybenzoate as preservative is justified; its effectiveness has been proven.

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.

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

C. Control of Starting Materials

The active substance is Detomidine 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.

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 (pharmaceuticals)

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 data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions. Additionally, the water content is determined prior to its use in the manufacture of the finished 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.

The in-use stability of the product is supported by appropriate stability data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

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Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 of Directive 2001/82/EC based on the essential similarity of Cepesedan 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 Cepesedan. Warnings and precautions as listed in the product literature are adequate to ensure safety of Cepesedan 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.

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 Cepesedan and the reference product Domosedan, results of preclinical and clinical studies are not required. The efficacy claims for Cepesedan 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 Cepesedan 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 Medicinal 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.

<None>