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

Revertor 5 mg/ml solution for injection for dogs

Date: February 2008

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0123/001/MR
Name, strength and pharmaceutical form	Revertor 5 mg/ml solution for injection for dogs
Applicant	CP-Pharma Handelsges. mbH Ostlandring 13 31303 Burgdorf Germany
Active substance	Atipamezole hydrochloride
ATC Vetcode	QV03AB90
Target species	Dogs
Indication for use	Atipamezole hydrochloride is a selective alpha 2-agonist and indicated for reversal of the sedative effects of medetomidine.

MODULE 2

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

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	24.10.2007
Date product first authorised in the Reference Member State (MRP only)	27.02.2007
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

Revertor from CP-Pharma, is a generic product to Antisedan marketed in Germany since 1991 (Reference number 23554.00.00). Revertor is a solution for injection and approved for reversal of the sedative effects of medetomidine in dogs.

Essential similarity of Revertor and the reference product Antisedan was demonstrated according to the relevant EU guidelines. The initial application for Antisedan 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 atipamezole hydrochloride 5 mg / ml and methyl parahydroxybenzoate, sodium chloride and water for injections.

The product is filled into 10 ml uncoloured glass vials. The vials are closed with rubber bungs. The bungs 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 a 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 atipamezole hydrochloride, an established active substance. 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 submitted to the authorities.

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

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.

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 day stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at 20 - 25°C.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

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 Revertor and the reference product Antisedan, results of pharmacological and toxicological tests are not required.

The applicant has made full reference to the SPC of the reference product Antisedan 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 Revertor. Warnings and precautions as listed in the product literature are adequate to ensure safety of Revertor to the user and the environment.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 of Directive 2001/82/EC based on essential similarity of Revertor and the reference product Antisedan, results of preclinical and clinical studies are not required. The efficacy claims for Revertor are equivalent to those of the reference product Antisedan.

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 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 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>