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

SEDATOR

Date: August 2007

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0119/001/MR
Name, strength and pharmaceutical form	Sedator, 1.0 mg/ml, solution for injection
Applicant	Eurovet Animal Health B.V. Handelsweg 25, 5531 AE Bladel, The Netherlands
Active substance(s)	Medetomidine hydrochloride
ATC Vetcode	QN05CM91
Target species	Cat, Dog
Indication for use	*In dogs and cats:* Sedation to facilitate handling. Premedication prior to general anaesthesia. *In cats:* In combination with ketamine for general anaesthesia for minor surgical procedures of short duration.

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	23 May 2007
Date product first authorised in the Reference Member State (MRP only)	20 October 2006
Concerned Member States for original procedure	AT, BE, CZ, DK, EL, ES, FI, FR, HU, IT, LT, LU, LV, NL, NO, PL, PT, SE, SI, SK

I. SCIENTIFIC OVERVIEW

Sedator from Eurovet Animal Health B.V., The Netherlands, is a generic product to Domitor (German reference number 32457.00.00) marketed in Germany since1995. In addition Domitor is authorised in Belgium, Denmark, Finland, France, United Kingdom, Ireland, The Netherlands, Norway and Sweden. Sedator is a solution for injection and approved for sedation to facilitate handling and as a premedication prior to general anaesthesia in dogs and cats. In cats it is also indicated for general anaesthesia for minor surgical procedures of short duration in combination with ketamine.

Essential similarity of Sedator and the reference product Domitor was demonstrated according to the Guideline for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMEA/CVMP/016/00-corr-FINAL). Therefore, a bioequivalence study was not required. The initial application for Domitor 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 Medetomidine hydrochloride 1 mg / ml and Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Sodium chloride and Water for injections.

The container/closure system consists of clear glass vials of 5, 10 and 20 ml with Teflon coated halogenated rubber stoppers. The stoppers are sealed with aluminium 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 preservatives 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 Medetomidine hydrochloride, an established active substance. The active substance is manufactured in accordance with the principle 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 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 studies on the active substance 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 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at + 30°C.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL) (*for pharmaceuticals only)*

As this is a generic application according to Article 13 of Directive 2001/82/EC based on the essential similarity of Sedator and the reference product Domitor, results of pharmacological and toxicological tests are not required.
The applicant has made full reference to the SPC of the reference product Domitor 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 Sedator. Warnings and precautions as listed in the product literature are adequate to ensure safety of Sedator to the users and the environment.

IV. CLINICAL ASSESSMENT (EFFICACY)

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

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 risk benefit profile for the target species is favourable and the quality and safety of Sedator 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>