MINISTERIO DE SANIDAD Y CONSUMO
agencia española de medicamentos y productos sanitarios

SUBDIRECCIÓN GENERAL
DE MEDICAMENTOS
DE USO VETERINARIO

Agencia Española de Medicamentos y Productos Sanitarios

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C/Campezo 1,
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

[DRAFT] PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DURNIT 1mg/ml solution for injection for dogs and cats

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0151/001/DC
Name, strength and pharmaceutical form	DURNIT 1mg/ml solution for injection for dogs and cats
Applicant	VETPHARMA ANIMAL HEALTH, S.L. Les Corts, 23.08028 Barcelona Spain
Active substance(s)	Medetomidine hydrochloride
ATC Vet code	QN05CM91.
Target species	Dogs and cats.
Indication for use	- Sedation in order to facilitate the restraint of animals during clinical examinations. - Premedication prior to general anaesthesia

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	08/09/2009
Date product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	DE

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

II. QUALITY ASPECTS

A. Composition

The product contains Medetomidine (as hydrochloride) 0.85 mg, Methyl parahydroxybenzoate (E 218), Propyl parahydroxybenzoate (E 216), Sodium chloride and Water for injections

The container/closure system are type I clear glass vials with 10 ml capacity. Vials are fitted with a bromobutyl stopper and sealed with an aluminium capsule. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and excipients are justified.

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 Medetomidine (as 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 updated edition of ASMF has been included.

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 Industrial Veterinaria, S.A. 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 days stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at +25°C.

H. Genetically Modified Organisms

J. Other Information

III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13, and bioequivalence with a reference product is not necessary, results of toxicological, pharmacological or clinical tests are not required.

The safety aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users and the environment.

III.A Safety Testing

Pharmacological Studies

The application is submitted in accordance with Article 13, generic application, and therefore pharmacological data are not presented.

Medetomidine is a sedative component which presents analgesic and myorelaxant properties. It is a selective agonist, specific and particularly effective for alpha-2-adrenergics receptors.

After intramuscular injection, medetomidine is rapidly and almost completely absorbed in the site of injection. Maximum plasma concentrations are reached within 15 and 20 minutes. Estimated plasma half-life is 1.2 hours for dogs and 1.5 hours for cats. Medetomidine is mainly oxidised in the liver, while a small amount is methylated in the kidneys. Metabolites are primarily excreted in urine.

Toxicological Studies

The application is submitted in accordance with Article 13, generic application, and therefore toxicological data are not presented.

User Safety

According to guideline EMEA/CVMP/543/03-FINAL this section does not apply to Marketing Authorisations granted in accordance with Article 13(1) generic application.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product is not necessary, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

As this product is administered parenteral and it contains the same active substance and excipients, at the same concentrations, than the reference product, the applicant is exempt of bioequivalence testing according to Guideline for the conduct of bioequivalence studies for veterinary medicinal products (EMEA/CVMP/016/00-Final).

IV.A Pre-Clinical Studies

The application is submitted in accordance with Article 13, generic application, and therefore preclinical data are not presented.

IV.B Clinical Studies

The application is submitted in accordance with Article 13, generic application, and therefore clinical data are not presented.

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 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 veterinary Heads of 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