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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

DEXMOPET solution for injection for dogs and cats [FR]

DEXMOPET 0.5 mg/ml solution for injection for dogs and cats [BE, BG, CY, CZ, DE, ES, IE, PL, PT, SK]

DEXMOPET vet 0.5 mg/ml solution for injection for dogs and cats [DK, NO, SE]

DATE: 19/12/2017

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0290/001/DC
Name, strength and pharmaceutical form	DEXMOPET solution for injection for dogs and cats
Applicant	VETPHARMA ANIMAL HEALTH, S.L. Les Corts, 23 08028 – BARCELONA Spain
Active substance(s)	Dexmedetomidine (as hydrochloride)
ATC Vetcode	QN05CM18
Target species	Dogs and cats
Indication for use	Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats. Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures. Premedication in dogs and cats before induction and maintenance of general anaesthesia.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC, as amended.
Date of completion of the decentralised procedure	28/04/2016
Concerned Member States for original procedure	BG, CZ, DE, DK, ES, IE, NO, PL, PT, SE, SK

I. SCIENTIFIC OVERVIEW

For public assessment reports for the first authorisation in a range:

The product contains 0.5 mg/ml of dexmedetomidine hydrochloride, indicated for:
Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.
Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures.
Premedication in dogs and cats before induction and maintenance of general anaesthesia.
The reference product is DEXDOMITOR 0.5 mg/ml solution for injection marketed by ORION CORPORATION, which has been authorized through centralized procedure on 30/08/2002. Bioequivalence with the reference product has been demonstrated.
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 reactions observed are indicated in the SPC[1].
The product is safe for the user, and for the environment, when used as recommended. Suitable warnings and precaution 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.

[1] SPC- Summary of Product Characteristics

II. QUALITY ASPECTS

A. Composition

The product contains 0,42 mg/ml of dexmedetomidine (as hydrochloride) as active substance and the following excipients: methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium chloride and water for injections.
The product is packaged as described in the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
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 dexmedetomidine 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.

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.
An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Based on information provided in support of this application, it is accepted that the test product is bioequivalent to the reference DEXDOMITOR 0.5 mg/ml solution for injection marketed by ORION CORPORATION.

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

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

Toxicological Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product and are also in compliance with the Commission decision of 30.4.2009 concerning, the marketing authorisations of veterinary medicinal products which contain the active substance "alpha2-adrenoreceptor agonist (romifidine, xylazine, detomidine or medetomidine), in the framework of Article 78 of Directive 2001/82/EC of the European Parliament and of the Council.

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)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because:

- the tested product and the reference product are bioequivalent,
- the excipients of the tested product are identical to the reference product.

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

IV.B Clinical Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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.