



College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

**Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands**

DECENTRALISED PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

Atipam 5.0 mg/ml, Solution for Injection for Cats & Dogs

Date Updated: October 2018

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0279/001/DC
Name, strength and pharmaceutical form	Atipam 5.0mg/ml, Solution for Injection for Cats and Dogs
Applicant	Eurovet Animal Health BV
Active substance	Atipamezole hydrochloride
ATC Vetcode	QV03AB90
Target species	Dogs and Cats
Indication for use	Atipamezole hydrochloride is a selective α -antagonist and indicated for reversal of the sedative effects of medetomidine and dexmedetomidine in cats and dogs.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary 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	04 March 2008
Date product first authorised in the Reference Member State (MRP only)	n/a
Concerned Member States for original procedure	Austria Belgium Czech Republic Denmark Finland France Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Slovakia Slovenia Spain Sweden

I. SCIENTIFIC OVERVIEW

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

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 slight reactions observed are indicated in the SPC. The product is safe for the user, 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 the active substance atipamezole hydrochloride and excipients methyl parahydroxybenzoate (E218), sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections

The container/closure system comprises a cardboard box with 1 clear glass type I vial of 5, 10, or 20 ml, with a teflon coated halogenated rubber stopper and aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and presence of 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.

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 atipamezole hydrochloride. Supporting data have been provided in the form of an Active Substance Drug Master File (ASMF). It is considered that the manufacturing process is adequately controlled and the active substance specification has been suitably justified. 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.

The excipients, methyl parahydroxybenzoate, sodium chloride, sodium hydroxide, hydrochloric acid and water for injections in bulk used in the manufacture of the product comply with European Pharmacopoeia monographs.

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

There are no intermediate products.

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 active substance when stored under the approved conditions.

Data support the 28-day shelf life after first opening the container.

H. Genetically Modified Organisms

Not applicable

J. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 28 days

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, 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.

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 / the environment / consumers

Toxicological Studies

As this is a generic application according to Article 13, 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.

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 / the environment / consumers

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows all potential routes of accidental administration. 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)

IV.A Pre-Clinical Studies

Pharmacology

The application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, no further information is required as it has already been presented for the reference product. Bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Tolerance in the Target Species of Animals

The application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, no further information is required as it has already been presented for the reference product. Bioequivalence with the

reference medicinal product has been demonstrated by appropriate bioavailability studies.

IV.B Clinical Studies

The application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, no further information is required as it has already been presented for the reference product. Bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

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 Heads of Veterinary Medicines 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.

•	30 August 2018	Change in RMS from UK to NL.
•	13 March 2015	Changes to the active substance master file.
•	05 June 2013	Renewal.
•	26 April 2013	Change of name and contact details of the QPPV.
•	16 February 2011	Change of Distributor.
•	21 August 2008	Variation to add three additional pack sizes of 4.8 kg, 6.4 kg and 8 kg.