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

Tramvetol 50 mg/ml solution for injection for dogs (AT BE CY CZ DE DK EE EL ES IE FI HU LT LV NL PL PT RO SE SK UK)

Tramvetol solution for injection for dogs (FR)

Tramadol Vet Virbac 50 mg/ml solution for injection for dogs (NO)

NL/V/0266/001/DC

Created: March 2022

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0266/001/DC
Name, strength and pharmaceutical form	Tramvetol 50 mg solution for injection
Applicant	VIRBAC 1ère avenue 2065 m LID 06516 Carros France
Active substance(s)	Tramadol (as hydrochloride)
ATC Vet code	QN02AX02
Target species	Dogs
Indication for use	For the reduction of mild postoperative pain.

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VIRBAC	DCP
	Publicly available assessment report

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	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	31 July 2019
Concerned Member States for original procedure	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, LT, LV, NO, PL, PT, RO, SE, SK, UK(NI)

I. SCIENTIFIC OVERVIEW

Tramvetol tablets is a generic application, the reference product is ALTADOL 50 mg/ml soluzione iniettabile per cani, which has been authorized in Italy since 9 July 2005 (marketing authorisation number A.I.C. n. 103703017). The Marketing Authorisation Holder of the reference product is Formevet S.r.l.
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. Qualitative and quantitative particulars

The proposed product is an aqueous veterinary medicinal product for parenteral administration. The product contains 50 mg/mL tramadol hydrochloride as active substance and the following excipients: sodium acetate trihydrate and water for injections.

Clear type I glass ampoules, containing 1.0 ml of finished product. The glass ampoules are in conformity with Ph. Eur. requirements.

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 results for three 40 L production batches have been provided. The maximum acceptable batch size is 200 L. The tests performed during production are described.

C. Control of Starting Materials

The active substance is tramadol hydrochloride, an established active substance described in the European Pharmacopoeia (monograph 1681). For the active substance the CEP procedure is followed. 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.

No materials of animal origin are contained or used in the manufacturing process of the veterinary medicinal product.

D. Control on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and the corresponding acceptance criteria are acceptable.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been submitted, demonstrating compliance with the proposed finished product specification

F. Stability

The re-test period of the substance is 3 years if stored in double polyethylene bags placed inside coated metal drums, as claimed on the Certificate of Suitability.

Stability data on the finished product have been provided up to 12 months of storage at long term and intermediate conditions and 6 months at accelerated storage conditions. Based on the submitted stability data for the drug product, the proposed shelf-life of 24 months is acceptable.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated (exemption of bioequivalence studies based on being essentially similar as the reference product), results of toxicological, pharmacological or clinical tests are not required.

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

Warnings and precautions as listed on the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users and the environment.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. User safety warnings are in line with comparable authorized products.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

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

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.

Summary of change	**Section updated**	**Approval date**
C.I.9.b – Change(s) in the safety database and/or major contractual arrangements for the fulfilment of pharmacovigilance obligations, and/or change of the site undergoing pharmacovigilance activities. (NL/V/0266/001/IA/001)	N/A	7 February 2020