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 tablets for dogs
(CY CZ DK EL ES IE LT LV NL PL PT RO SE SK UK)

Tramvetol 43.9 mg tablets for dogs (AT BE DE EE FI HU FR)

Tramadol Vet Virbac 50 mg tablets for dogs (NO)

NL/V/0267/001/DC

Created: March 2022

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0267/001/DC
Name, strength and pharmaceutical form	Tramvetol 50 mg tablets
Applicant	VIRBAC 1ère avenue 2065 m LID 06516 Carros France
Active substance(s)	Tramadol (as hydrochloride)
ATC Vet code	QN02AX02
Target species	Dogs (weighing more than 6.25 kg)
Indication for use	For the reduction of acute and chronic mild soft tissue and musculoskeletal pain.

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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 compresse solubili per cani, which has been authorized in Italy since 9 July 2005 (marketing authorisation number A.I.C. n. 103703029 & 103703031). 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 tablet contains 50 mg tramadol hydrochloric acid and the following excipients: cellulose microcrystalline, pregelatinized maize, saccharin sodium, meat flavour, magnesium stearate and colloidal anhydrous silica. The tablet is scored and meant to be broken into equal halves.

The products are packed in PVC/PE/PVDC-Al blisters.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

A bioequivalence study is waived since the test and the reference product are identical in composition and manufacture.

B. Method of Preparation of the Product

The product is manufactured in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. Suitable validation results on three commercial scale batches have been provided.

The tests performed during production are described, and are regarded to be acceptable.

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C. Control of Starting Materials

The active substance is tramadol hydrochloric acid is an established active substance described in the European Pharmacopoeia.
The active substance is manufactured in accordance with the principles of good manufacturing practice. For the manufacture of the active substance a CEP procedure is used and a valid version of the CEP is provided.
The active substance specification is adequate in order to control the quality of the material. Microbiological quality is included in the drug substance specification as additional test. Batch analytical data demonstrating compliance with the proposed specification have been provided.
All excipients are in conformity with the Ph. Eur. requirements and additional functionality related characteristics with the exception of the flavour for which in-house specifications are used.
The packaging is in conformity with the Ph. Eur. and EU Food Directive.
The magnesium stearate is of vegetable origin.

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.
Validation data for the analytical methods have been provided, as well as batch analytical data from the proposed production site, demonstrating compliance with the specification.

F. Stability

According to the CEP a re-test period of 3 years is granted.

Stability data on the finished product have been provided in accordance with applicable European guidelines. The provided stability data for the finished product is sufficient to extrapolate the shelf-life to two year without special storage conditions.

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 (based on having the same quantitative and qualitative composition and the same pharmaceutical form as the reference product), 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 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.

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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.

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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/0267/001/IA/001)	N/A	7 February 2020
B.II.a.3.a.1 – Changes in the composition (excipients) of the finished product; Changes in components of the flavouring; replacement (NL/V/0267/001/IA/002)	N/A	7 November 2021