



FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

ZOLETIL 50 (25 mg/ml+25 mg/ml) lyophilisate and solvent for solution for injection for dogs and cats (FR / NL / PL / IE / MT)

ZOLETIL 50 VET 25 mg/ml+25 mg/ml lyophilisate and solvent for solution for injection for dogs and cats (SE / FI)

ZOLETIL 100 (50 mg/ml+50 mg/ml) lyophilisate and solvent for solution for injection for dogs and cats (FR / AT / DE / IE / MT / NL / PL / RO / UK)

ZOLETIL 100 VET 50 mg/ml+50 mg/ml lyophilisate and solvent for solution for injection for dogs and cats (SE / FI)

Date:

30/03/2016

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0283/001-002/DC
Name, strength and pharmaceutical form	ZOLETIL 50 (25 mg/ml+25 mg/ml) lyophilisate and solvent for solution for injection for dogs and cats (FR / NL / PL / IE / MT) ZOLETIL 50 VET 25 mg/ml+25 mg/ml lyophilisate and solvent for solution for injection for dogs and cats (SE / FI) ZOLETIL 100 (50 mg/ml+50 mg/ml) lyophilisate and solvent for solution for injection for dogs and cats (FR / AT / DE / IE / MT / NL / PL / RO / UK) ZOLETIL 100 VET 50 mg/ml+50 mg/ml lyophilisate and solvent for solution for injection for dogs and cats (SE / FI)
Applicant	VIRBAC 1ère avenue 2065 m L.I.D 06516 Carros cedex FRANCE
Active substance(s)	Tiletamine Zolazepam
ATC Vetcode	QN01AX99
Target species	Dogs and cats.
Indication for use	General anaesthesia.

MODULE 2

The Summaries of Product Characteristics (SPC) for these products are available on the website <http://www.anmv.anses.fr/>

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic applications in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	17/12/2015
Concerned Member States for original procedure	<p>ZOLETIL 50 (25 mg/ml+25 mg/ml) lyophilisate and solvent for solution for injection for dogs and cats (FR / NL / PL / IE / MT)</p> <p>ZOLETIL 50 VET 25 mg/ml+25 mg/ml lyophilisate and solvent for solution for injection for dogs and cats (SE / FI)</p> <p>ZOLETIL 100 (50 mg/ml+50 mg/ml) lyophilisate and solvent for solution for injection for dogs and cats (FR / AT / DE / IE / MT / NL / PL / RO / UK)</p> <p>ZOLETIL 100 VET 50 mg/ml+50 mg/ml lyophilisate and solvent for solution for injection for dogs and cats (SE / FI)</p>

I. SCIENTIFIC OVERVIEW

The products are 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 products can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The products are safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy claims for these products are equivalent to those of the reference products.

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

II. QUALITY ASPECTS

A. *Composition*

The lyophilisat vial contains tiletamine (as hydrochloride) (125 mg/vial for ZOLETIL 50 mg/vial and 250 mg/vial for ZOLETIL 100) and zolazepam (as hydrochloride) (125 mg/vial for ZOLETIL 50 mg/vial and 250 mg/vial for ZOLETIL 100). The excipients are anhydrous sodium sulfate and lactose monohydrate. The solvent vial contains water for injection.

The lyophilisate and the solvent are packed in colourless glass vials. The particulars of the containers and of the controls performed are provided and conform to the regulation.

The products are established pharmaceutical form and their development is adequately described in accordance with the relevant European guidelines.

B. *Method of Preparation of the Product*

The products are manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the products have been presented in accordance with the relevant European guidelines.

C. *Control of Starting Materials*

The active substances are tiletamine hydrochloride and zolazepam hydrochloride, established active substances. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substances specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with the 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 these products.

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 products.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production sites have been provided demonstrating compliance with the specification.

G. *Stability*

Stability data on the active substances 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 in the SPC has been supported by appropriate data.

H. *Genetically Modified Organisms*

Not applicable.

J. *Other Information*

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Based on exemption 7.1.b) of “Guidelines on the conduct of bioequivalence studies for veterinary medicinal products” (EMA/CVMP/016/00-Rev.2), it is accepted that the test products are bioequivalent to the reference products ZOLETIL 50 and ZOLETIL 100 marketed by VIRBAC.

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the applicant shall not be required to provide the results of pharmacological tests.

The pharmacological aspects of these products are identical to those of the reference products.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, the applicant shall not be required to provide the results of toxicological tests.

The toxicological aspects of these products are identical to the reference products’ ones.

User Safety

The applicant has not provided a user safety assessment which is acceptable because the tested products and the reference products have similar formulations and are bioequivalent.

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

Ecotoxicity

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

III.B Residues documentation

These products are intended for non-food producing species, thus there was no necessity to provide data for this section.

IV. CLINICAL ASSESSMENT (EFFICACY)

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because the tested products and the reference products have similar formulations.

The tolerance aspects of these products are identical to the reference product.

Based on the conclusion made for the reference product, the product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

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 these products are equivalent to those of the reference products.

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.