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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vetbuton 100 mg/ml solution for injection for cattle, pigs, horses, sheep and goats

DATE : 10/07/2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0324/001/DC
Name, strength and pharmaceutical form	Vetbuton 100 mg/ml solution for injection for cattle, pigs, horses, sheep and goats
Applicant	Vet-Agro Multi-Trade Company Sp. z o.o. Gliniana 32, 20-616 Lublin Poland
Active substance(s)	Menbutone
ATC Vetcode	QA05AX90
Target species	Cattle, pigs, horses, sheep, goats.
Indication for use	Stimulation of hepato-digestive activity in case of digestive disorders and hepatic insufficiency.

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 original decentralised procedure	03/07/2019
Concerned Member States for original procedure	BE, ES, HR, NL, PT, RO, SE, SI

I. SCIENTIFIC OVERVIEW

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, the consumer of foodstuffs from treated animals 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 100 mg/ml of menbutone and the following excipients: chlorocresol, sodium metabisulfite (E223), edetic acid (as disodium edetate), ethanolamine, and water for injections.

The packaging of the finished product is as described on 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.
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 menbutone, 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.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Based on exemption 7.1. a) and 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 product is bioequivalent to the reference product GENABILINE Solution Injectable in cattle, pigs, horses, sheep and goats marketed by BOEHRINGER INGELHEIM.

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 this product are identical to those of the reference product

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' ones.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the risk for the user when the product is used as recommended, is very low.

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

Environmental Risk Assessment

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

III.B Residues documentation

Residue Studies

No depletion study was performed following administration of the new product Vetbuton 100 mg/ml solution injectable for cattle, pigs, horses, sheep and goats.

MRLs

The active substance, menbutone, is included in table 1 of the MRL regulation 37/2010, as follows,

Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification	Regulation
Not applicable	Bovine, ovine, caprine, porcine, *Equidae*	No MRL required	Not applicable	No entry	No entry	37/2010 of 22.12.2009

An acceptable daily intake (ADI) was defined for menbutone. It is 60 µg/kg bw (*i.e.* 3.6 mg/person).

b. excipients

The MRL status of excipients of the product is indicated in the following table.

Excipient	MRL status
Chlorocresol	Table1, no MRL required, all food producing species
Sodium metabisulfit (E223)	Food additive
Edetic acid	Table1, no MRL required, all food producing species
Ethanolamine	Table1, no MRL required, all food producing species
Purified water	Out of scope list

Withdrawal Periods

No depletion study was performed with the new product. The same withdrawal periods can be accepted.

Meat and offal: zero days
Milk: zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

Tolerance in the Target Species of Animals

The applicant has not provided tolerance study which is acceptable because the safety profiles of the excipients are well established and the tested product and the reference product have similar formulations. The tolerance aspects of this product 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.

Resistance

Not relevant.

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 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.