Institute for State Control of Veterinary Biologicals and Medicines
Hudcova 56a, 621 00 Brno, Czech Republic

(Reference Member State - CZ)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

SEDAN 35 mg/ml oral gel for horses and dogs

MODULE 1

PRODUCT SUMMARY

EU Procedure number	CZ/V/0174/001/MR
Name, strength and pharmaceutical form	SEDAN 35 mg/ml oral gel for horses and dogs (CZ, BE, BG, CY, DE, EL, ES, HR, HU, IT, LT, LV, NL, PL, PT, RO, SK) PROMASED 35 mg/ml oral gel for horses and dogs (AT, FR) PROMASED (EE, DK, NO) Promased Vet (SE)
Applicant	Bioveta, a.s. Komenského 212 683 23 Ivanovice na Hané Česká republika
Active substance(s)	Acepromazine 35.0 mg
ATC vet code	QN05AA04
Target species	Horses (non food-producing), dogs
Indication for use	In horses and dogs. For sedation and anaesthetic premedication.

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 13.3. of Directive 2001/82/EC, as amended.
Date of completion of the original mutual recognition procedure	27/04/2022
Date product first authorised in the Reference Member State (MRP only)	28/08/2018
Concerned Member States for original procedure	AT, BE, BG, CY, DE, DK, EE, EL, ES, FR, HR, HU, IT, LT, LV, NL, NO, PL, PT, RO, SE, SK

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. Qualitative and quantitative particulars

The product contains Aceptomazine (as maleate) 35 mg/mL and the following excipients: Methylparaben, Propylparaben, Glycerol, Hydroxyethylcellulose, Sodium acetate trihydrate, Sodium cyclamate and Purified water.

The container-closure system consists of

- 12 mL PE applicator, fitted with a PE cover and a PP dosing ring containing 10 mL of the product
- 1 mL PP applicator fitted with a HDPE cap, a polyisoprene cuff, a polystyrene plunger containing 1 mL of the product

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 at a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. 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 Acepromazin maleate is an established active substance that is not described in European Pharmacopoeia. The company established in-house specification that is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

The active substance is manufactured in accordance with the principles of good manufacturing practice. Scientific data have been provided in a form of ASMF. The synthesis and controls in place are compliant with the requirements of the relevant EU guidelines, Ph. Eur. texts and general monographs.

No material of human or animal origin are used during manufacture of the API or finished product. No TSE risk or viral safety issue are thus identified.

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 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.

F. Stability

Stability data on the active substance have been provided within the ASMF. The data are 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, no storage precautions are needed.

G. Other Information

BEQ studies are provided. Refer to part IV.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13.1 of Directive 2001/82/EC as amended, results of safety tests are not required.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. 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 relevant CVMP/VICH guidelines. The Environmental Risk Assessment may stop in Phase I and Phase II is not required. The product will be used to treat a small number of individual non-food animals.
It can be concluded that the product is not expected to pose a risk for the environment when used under indications and precautions recommended in the SPC and product literature.

III.B Residues documentation

The applicant has provided generic application in accordance with Article 13.3. of Directive 2001/82/EC, as amended.

No residue depletion studies were conducted.

MRLs

The active substance acepromazine is not included in Table 1 of the Annex of Commission Regulation No 37/2010, however the substance is mentioned on the "List of substances essential for the treatment of Equidae and substances bringing added clinical benefit compared to other treatment options available for Equidae" in Commission Regulation (EU) No 122/2013 of 12 February 2013 amending Regulation (EC) No 1950/2006.

Withdrawal Periods

The text of the withdrawal periods is following:
Horses: Do not use in horses whose meat, offal and milk are intended for human consumption. The treatment must be recorded in the horse's passport.

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

None