MEB agency / Veterinary Medicinal Products Unit
The Netherlands

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

Ventimaxx 25 microgram/ml oral solution for horses

NL/V/0425/001/DC

PRODUCT SUMMARY

EU procedure number	NL/V/0425/001/DC
Name, strength and pharmaceutical form	Ventimaxx 25 microgram/ml oral solution for horses
Applicant	Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden The Netherlands
Active substance(s)	clenbuterol hydrochloride
ATCvet code	QR03CC13
Target species	horses
Indication for use	Treatment of respiratory disease in horses where it is considered that airway obstruction due to bronchospasm and/or accumulation of mucus is a contributing factor, and improved mucociliary clearance is desirable.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application according to Art. 18 of Regulation (EU) 2019/6 as amended.
Reference product (RP) Marketing authorisation holder Member states where the RP is or has been authorised Marketing authorisation number EU procedure number Date of authorisation	Ventipulmin siroop voor paarden Boehringer Ingelheim Vetmedica GmbH AT, BE, DE, FR, IE, IT, NL, SE, UK(NI) REG NL 2529 - 16-03-1990
Date of completion of the original decentralised procedure	2 April 2025
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, RO, SE, SI, SK, UK(NI)

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

Ventimaxx 25 microgram/ml oral solution for horses is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.
It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

Ventimaxx 25 microgram/ml oral solution for horses 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 VMP was demonstrated according to the claims made in the SPC.

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

The safety and efficacy aspects of *Ventimaxx 25 microgram/ml oral solution for horses* are based on bioequivalence with the reference product *Ventipulmin siroop voor paarden*, which has been authorized in The Netherlands since 16 March 1990. The marketing authorisation holder of the reference product is Boehringer Ingelheim Vetmedica GmbH Germany. Warnings, statements and precautions are adopted from the reference product. Additional statements have added, based on increased knowledge and the current state of science.

2. QUALITY DOCUMENTATION

A. Composition

The veterinary medicinal product is an oral solution that contains Clenbuterol hydrochloride as drug substance (0.025 mg/ml). The excipients are Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Carbomer (974P), Sucrose, Macrogol 400, Glycerol, Ethanol (96%), Trolamine and Water, purified.

The container/closure system is a white plastic bottle, closed with a child resistant cap and a syringe adaptor. A co-packaged 25 ml plastic syringe is also provided.

The choice of the formulation is well justified. The qualitative composition of the generic veterinary medicinal product is the same as the reference product, except for the type of thickener agent. The change has been adequately justified. The type of preservatives and their concentrations are the same as per reference product, and the preservative efficacy test has been conducted as per Ph.Eur. 5.1.3. A Bioequivalence study is not necessary from a quality point of view as per the EMA Guideline on the conduct of bioequivalence studies for veterinary medicinal products.

The veterinary medicinal product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines. The veterinary medicinal product is packed in a multidose container. The differences between the proposed and the reference product on the container and dosing system have been adequately justified. Dosing accuracy has been demonstrated as per Ph.Eur. 2.9.27.

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 manufacturing process description, including IPC's, has been adequately provided. The proposed bulk holding time is supported by data.

The manufacturing process of the finished product is non-standard (i.e. unit dose products containing API ≤2.0% of the composition of the finished product). Nevertheless, an acceptable justification has been provided for the applicant to justify that the proposed manufacturing process can be considered as standard in this particular case.

Process validation data on three commercial batches have been presented in accordance with the relevant European guidelines. The post-approval validation scheme for the remaining batches has been submitted as per Annex I of the GL on Process validation for finished products.

C. Control of Starting Materials

The active substance is Clenbuterol hydrochloride, an active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice. An ASMF is used for the drug substance. The specification of the drug substance by the DPM is in line with the ASMF.

The excipients are in conformity with the Ph.Eur. requirements.

The different container closure systems, including the dosing device (syringe), have been sufficiently described. Specifications have been included and are acceptable.

None of the starting materials used are affected by the Note for Guidance on TSE/BSE.

D. Control on intermediate products

N.A.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The specification limits at release and shelf-life are acceptable.

The analytical methods of the drug product specification have been adequately described and validated.

F. Stability

The information on re-test period and storage conditions of the drug substance are in line with the ASMF of the active substance manufacturer.

Stability data has been submitted for three batches of the proposed finished product. The results at the long-term condition meet the specification requirements. However, OOS for related substances are found under accelerated stability condition. The proposed shelf-life of 36 months with a storage claim of “do not store above 30°C” is justified based on the provided data. The storage claim is also justified based on the freeze-thaw studies that demonstrate that the product does not require protection against freezing.

The proposed in-use shelf life of 3 months can be accepted based on the data provided.

Photostability studies for the VMP, conducted as per VICH GL5, have been provided and show that the finished product is not sensitive to light. No light storage claim is needed for the generic VMP.

G. Other Information

The control of the residual solvents in the finished product is acceptable and in line with the information provided in Part 2C.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 (and bioequivalence with the reference VMP has been demonstrated, results of toxicological, pharmacological and clinical tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP 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 VMP to users and the environment.

A. Safety Testing

User safety

Being a generic procedure the applicant refers to the reference product for information on this section.
Additionally, the applicant has provided a user safety assessment in compliance with the relevant guideline. Combined with increased knowledge and the current state of science, warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

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 VMP will only be used in individual animals, in the food producing animals horses.

The VMP is not expected to pose an unacceptable risk for the environment when used according to the SPC.

B Residues documentation

Residue Studies

Being a generic application submitted according to Article 13(1) of Directive 2001/82/EC as amended and bioequivalence with the reference product has been established, results of residue studies are not required.

MRLs

Clenbuterol hydrochloride is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Equidae	
Muscle	0.1 microgram/kg
Liver	0.5 microgram/kg
Kidney	0.5 microgram/kg

Withdrawal Periods

The withdrawal period of Ventimaxx 25 microgram/ml oral solution for horses is identical to the withdrawal period of the reference product Ventipulmin siroop voor paarden REG NL 2529.
Based on the data provided above, a withdrawal period of 28 days is justified.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with the reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

None

Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	Approval date

Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	Supporting information	Approval date