Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Gerichtstraße 49
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(Germany)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Clenovet 0.025 mg/ml oral gel for horses

Date:01 October 2025

PRODUCT SUMMARY

EU procedure number	DE/V/0353/001/MR
Name, strength and pharmaceutical form	Clenovet 0.025 mg/ml oral gel
Applicant	Serumwerk Bernburg AG Hallesche Landstrasse 105 B 06406 Bernburg, Germany
Active substance(s)	Clenbuterol hydrochloride
ATC vetcode	QR03CC13
Target species	Horse
Indication for use	In-feed use Respiratory diseases associated with bronchospasm, such as subacute and chronic bronchitis and bronchiolitis, chronic obstructive pulmonary disease (COPD), supportive in acute bronchitis and bronchopneumonia.

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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*	Application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Ventipulmin
Marketing authorisation holder	Boehringer Ingelheim Vetmedica GmbH
Marketing authorisation number	4968.00.02
Date of authorisation	11 November 1985
Date of completion of the original mutual recognition procedure	01 October 2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	11 February 2014
Concerned Member States for original procedure Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	AT, BE, CZ, ES, FR, HU, IT, NL, RO, SK
Concerned Member States for subsequent recognition procedure	N/A

*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

The veterinary medicinal product (VMP) 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.

The VMP 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 VMP can be assumed according to the claims made in the SPC.

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

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains the active substance clenbuterol hydrochloride (0.025 mg/ml), the antimicrobial preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate and the excipients carbomer 974 P, sucrose, macrogol 400, glycerol 85 %, ethanol 96 %, sodium hydroxide and purified water.

The container/closure system consists of a bottle of high-density polyethylene and a cap of polypropylene with a polyethylene liner.

Details of the device with which the VMP will be used are provided, as applicable.

The choice of the formulation and presence of preservatives are justified.

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

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

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

C. Production and control of starting materials

The active substance is clenbuterol hydrochloride, an established substance described in the European Pharmacopeia. 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.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

D. Control tests carried out on isolated intermediates during the manufacturing process

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 VMP.

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 tests

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 and in-use stability of the VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 results of toxicological and residue 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 product to users, the environment and consumers.

A. Safety tests

Pharmacological studies

See part 4.

Toxicological studies

As this is a generic application submitted according to Article 18 of Regulation (EC) No 2019/6, documentation on toxicity is not required.

User safety

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The applicant has provided a user safety assessment in compliance with the current CVMP guidance, "Guideline on user safety for pharmaceutical veterinary medicinal products" (EMA/CVMP/543/03-Rev.1), which shows risks that lead to a risk communication in accordance with the current SPC of the national VMP Clenovet but are supplemented with warnings to protect pregnant users and to inform about adverse effects of clenbuterol..

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

Environmental Risk Assessment

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 be used to treat a small number of animals in a flock or herd.

B. Residues documentation

Residue tests

This application is for a generic product, submitted in accordance with Article 18 of Regulation (EU) No. 2019/6. No residue depletion studies were conducted because the product is essentially similar to the reference product based on its composition and pharmaceutical form.

Maximum Residue Limits

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

Pharmacologically active substance	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Clenbuterol hydrochloride	Clenbuterol	Bovine, *Equidae*	0,1 µg/kg 0,5 µg/kg 0,5 µg/kg	Muscle Liver Kidney	Agents acting on the nervous system/ Agents acting on the nervous system
		Bovine	0,05 µg/kg	Milk	

The excipients listed in section 2. of the SPC are either allowed substances for which Table 1 of the Annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

Withdrawal Periods

A withdrawal period of 28 days for meat in horses matches that for the reference product and is justified. The withdrawal period text in the product information is as follows:

Horses:

Meat and offal:

For a treatment period of up to 10 days: 28 days.

Do not use for more than 10 days in animals producing food for human consumption.

Not authorised for use in animals producing milk for human consumption.

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 a reference VMP can be assumed, 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.