[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clenovet 0.025 mg/ml oral gel for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Clenbuterol hydrochloride 0.025 mg
(equivalent to 0.022 mg Clenbuterol)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	2.02 mg
Propyl parahydroxybenzoate (E216)	0.26 mg
Carbomer 974 P	/
Sucrose	/
Macrogol 400	/
Glycerol 85%	/
Ethanol 96%	/
Sodium hydroxide (E524)	/
Water, purified	/

Translucent, whitish, viscous gel.

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

Respiratory diseases associated with bronchospasm, such as subacute and chronic bronchitis and bronchiolitis, chronic obstructive pulmonary disease (COPD), supportive in acute bronchitis and bronchopneumonia.

3.3 Contraindications

Do not use in
- hyperthyroidism,
- tachycardic cardiac arrhythmias,
- cases of hypersensitivity to the active substance or any of the excipients

Please also refer to section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Special precautions should be taken in case of halothane anaesthesia, since the heart function can show increased sensitivity to catecholamines.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains clenbuterol, a beta-agonist, which may cause adverse effects such as increased heart rate.
People with known hypersensitivity to clenbuterol hydrochloride or any of the excipients should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may cause embryotoxicity. Pregnant women should take care when handling the veterinary medicinal product. Wear gloves to avoid skin contact.
Avoid contact with skin, eyes or mucous membranes. Immediately after accidental contact with the veterinary medicinal product, wash areas of skin thoroughly with plenty of soap and water. In case of accidental eye contact, flush thoroughly with clean water.
If symptoms occur after contact, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink when using the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horse:

Uncommon (1 to 10 animals/ 1 000 animals treated):	heavy sweating
Undetermined frequency (cannot be estimated from the available data):	muscle tremor
	tachycardia
	restlessness
	fatigue
	urticaria
	increased bleeding tendency*

* during surgery

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

In pregnant mares, treatment should be discontinued 1 to 2 days before the expected date of birth or if there are signs of the impending birth. Since clenbuterol hydrochloride is excreted in milk, the veterinary medicinal product should not be administered to lactating mares with foals up to the age of two months.

3.8 Interaction with other medicinal products and other forms of interaction

Enhanced effects including more frequent adverse events when used concomitantly with glucocorticoids, β_2-sympathomimetics, anticholinergics and methylxanthines.
Increased risk of ventricular arrhythmias when administered concomitantly with halogenated anaesthetics (isoflurane, methoxyflurane). Increased risk of arrhythmia with simultaneous administration of digitalis glycosides. Weakening the effect of tocolytics (oxytocin, prostaglandin $F_{2\alpha}$).

3.9 Administration routes and dosage

For in feed use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The veterinary medicinal product is administered with a small quantity of food.

Administer 0,8 µg clenbuterol hydrochloride per kg body weight (i.e. 0.7 micrograms clenbuterol per kg bodyweight) corresponding to 4 ml of the veterinary medicinal product per 125 kg body weight or 16 ml of the veterinary medicinal product per 500 kg body weight twice daily at intervals of 12 hours (minimum 8 hours).
Each dosage pumpstroke delivers 4 ml of gel.
The pump needs to be primed before the first use only. Prime the pump by pressing twice and discard the retrieved gel.

Duration of treatment:
10-14 days in acute or subacute conditions, in chronic cases over a longer period of time. If signs improve significantly, the dosage can be reduced by half after approximately 10 days.
For horses for human consumption please also refer to section 3.12.

Before use, the cap of the bottle is removed and then the metering pump is screwed onto the bottle thread. Pressing the metering pump empties 4 ml of gel in one stroke. After use, the metering pump is unscrewed again, and the bottle is closed by screwing down the cap.

This veterinary medicinal product is intended for individual animal treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdosage can lead to more severe side effects (threatening cardiac arrhythmias). In case of overdosage, administer β-adrenolytics (propranolol, carazolol) as an antidote.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QR03CC13

4.2 Pharmacodynamics

Clenbuterol hydrochloride is a β2-sympathomimetic that is used in obstructive bronchial diseases due to its bronchodilating effect. Its pharmacological effect is based on binding to β2-adrenoceptors of smooth muscle cells, which leads to relaxation of the bronchial muscles via activation of adenylate cyclase, formation of cyclic adenosine monophosphate and activation of protein kinases. Clenbuterol hydrochloride inhibits IgE-dependent histamine release from mast cells in vitro. Clenbuterol hydrochloride has an anti-inflammatory effect by modulating pro-inflammatory cytokines in the early inflammatory reaction in the airways. Clenbuterol hydrochloride enhances mucociliary clearance in the airways.
By binding to β2-adrenoceptors of the uterine musculature and peripheral blood vessels, clenbuterol hydrochloride has a tocolytic and vasodilating effect. It increases glycogenolysis in the liver and stimulates the release of insulin. High doses increase protein synthesis in the skeletal muscles.

4.3 Pharmacokinetics

After oral administration, clenbuterol hydrochloride is almost completely bioavailable. In horses, maximum plasma concentrations are reached after about two hours.
Clenbuterol hydrochloride is rapidly distributed in the tissues, where concentrations are sometimes significantly higher than in plasma. A volume of distribution of 1.6 l/kg was determined in horses.
Clenbuterol hydrochloride is partially degraded in the liver to ineffective metabolites and is predominantly eliminated renally. Half-lives of 12 to 20 hours were measured in horses.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 12 weeks.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

HDPE bottle sealed with a screw cap made of PP with PE sealing insert, separately enclosed a metering pump made of polyethylene/polypropylene.

Pack size:
1 bottle with 355 ml gel and 1 metering pump.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD month YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for 1 bottle with 355 ml gel and 1 metering pump

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clenovet 0.025 mg/ml oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Clenbuterol hydrochloride 0.025 mg
(equivalent to 0.022 mg Clenbuterol)

3. PACKAGE SIZE

355 ml bottle with metering pump

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For in feed use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 weeks.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG (logo)

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1 bottle with 355 ml gel and metering pump

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clenovet 0.025 mg/ml oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Clenbuterol hydrochloride 0.025 mg
(equivalent to 0.022 mg Clenbuterol)

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

For in feed use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 weeks, use by ….

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG (logo)

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clenovet 0.025 mg/ml oral gel for horses

2. Composition

Each ml contains:

Active substance:
Clenbuterol hydrochloride 0.025 mg
(equivalent to 0.022 mg Clenbuterol)

Excipients:
Methyl parahydroxybenzoate (E218) 2.02 mg, Propyl parahydroxybenzoate (E216) 0.26 mg

Translucent, whitish, viscous gel.

3. Target species

Horses

4. Indications for 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.

5. Contraindications

Do not use in
- hyperthyroidism,
- tachycardic cardiac arrhythmias,
- cases of hypersensitivity to the active substance or any of the excipients

Please also refer to section 6 (Special warnings, Pregnancy and lactation).

6. Special warnings

Special precautions for safe use in the target species:
Special precautions should be taken in case of halothane anaesthesia, since the heart function can show increased sensitivity to catecholamines.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains clenbuterol, a beta-agonist, which may cause adverse effects such as increased heart rate.
People with known hypersensitivity to clenbuterol hydrochloride or any of the excipients should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may cause embryotoxicity. Pregnant women should take care when handling the veterinary medicinal product. Wear gloves to avoid skin contact.
Avoid contact with skin, eyes or mucous membranes. Immediately after accidental contact with the veterinary medicinal product, wash areas of skin thoroughly with plenty of soap and water. In case of accidental eye contact, flush thoroughly with clean water.

If symptoms occur after contact, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink when using the veterinary medicinal product.
Wash hands after use.

Pregnancy and lactation:
In pregnant mares, treatment should be discontinued 1 to 2 days before the expected date of birth or if there are signs of the impending birth. Since clenbuterol hydrochloride is excreted in milk, the veterinary medicinal product should not be administered to lactating mares with foals up to the age of two months.

Interaction with other medicinal products and other forms of interaction:
Enhanced effects including more frequent adverse events when used concomitantly with glucocorticoids, β_2-sympathomimetics, anticholinergics and methylxanthines.
Increased risk of ventricular arrhythmias when administered concomitantly with halogenated anaesthetics (isoflurane, methoxyflurane). Increased risk of arrhythmia with simultaneous administration of digitalis glycosides. Weakening the effect of tocolytics (oxytocin, prostaglandin $F_{2\alpha}$).

Overdose:
Overdosage can lead to more severe side effects (threatening cardiac arrhythmias). In case of overdosage, administer β-adrenolytics (propranolol, carazolol) as an antidote.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horse:

Uncommon (1 to 10 animals/ 1 000 animals treated):	heavy sweating
Undetermined frequency (cannot be estimated from the available data):	muscle tremor
	tachycardia
	restlessness
	fatigue
	urticaria
	increased bleeding tendency*

* during surgery

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For in feed use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The veterinary medicinal product is administered with a small quantity of food.

Administer 0,8 µg clenbuterol hydrochloride per kg body weight (i.e. 0.7 micrograms clenbuterol per kg bodyweight) corresponding to 4 ml of the veterinary medicinal product per 125 kg body weight or 16 ml of the veterinary medicinal product per 500 kg body weight twice daily at intervals of 12 hours (minimum 8 hours).
Each dosage pumpstroke delivers 4 ml of gel.
The pump needs to be primed before the first use only. Prime the pump by pressing twice and discard the retrieved gel.

Duration of treatment:
10-14 days in acute or subacute conditions, in chronic cases over a longer period of time. If signs improve significantly, the dosage can be reduced by half after approximately 10 days.
For horses for human consumption please also refer to section 10.

Before use, the cap of the bottle is removed and then the metering pump is screwed onto the bottle thread. Pressing the metering pump empties 4 ml of gel in one stroke. After use, the metering pump is unscrewed again, and the bottle is closed by screwing down the cap.

This veterinary medicinal product is intended for individual animal treatment.

9. Advice on correct administration

See above under section “8. Dosage for each species, routes and method of administration”.

10. Withdrawal periods

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.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton box after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 12 weeks.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number

Pack size:
1 bottle with 355 ml gel and 1 metering pump.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany
Phone: +49 (0)3471 860 4300

Local representatives and contact details to report suspected adverse events: