SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dilaterol 25 micrograms/ml syrup for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Clenbuterol hydrochloride 25 micrograms
(corresponding to 22 micrograms 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	0.26 mg
Carbomer 974P	
Sucrose	
Macrogol 400	
Glycerol (85%)	
Ethanol (96%)	
Sodium hydroxide	
Water, purified	

Clear colourless syrup

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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. To be used alone or as adjuvant therapy.

3.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance or any of the excipients.
Do not use in horses with known cardiac disease.
For use during pregnancy or lactation see section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In cases accompanied by bacterial infection the administration of antimicrobial agents is recommended.
In case of glaucoma the product must only be used after a careful risk-benefit assessment.
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 product contains clenbuterol hydrochloride, a beta-agonist.

Wear gloves to avoid skin contact. In case of accidental skin contact, wash affected area thoroughly. If irritation occurs/persists seek medical advice. Wash hands thoroughly after using the product.

Take care to avoid eye contact. In the case of accidental eye contact, flush thoroughly with clean water and seek medical advice.

Do not eat, drink or smoke when using this product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to clenbuterol should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Rare (1 to 10 animals / 10,000 animals treated):	Restlessness; Tachycardia, Hypotension[a]; Muscle tremor; Hyperhidrosis[b]

[a] slight
[b] mainly neck region

These adverse events are typical for β-agonists.

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:
If used during pregnancy, treatment must be discontinued a minimum of 4 days before the expected time of delivery, since uterine contractions may be abolished or labour may be prolonged under its influence.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. A nursing foal ingests a high volume of milk relative to its body weight. Therefore, during lactation an effect of the active substance excreted in milk in the nursing foal cannot be definitely excluded.

3.8 Interaction with other medicinal products and other forms of interaction

The product antagonises the effects of prostaglandin F2 -alpha and oxytocin.
The product is antagonised by β-adrenergic blocking agents.
Do not administer concurrently with other beta-adrenergic agents.
During the use of both local and general anaesthetics one cannot exclude a further vascular dilatation and fall of blood pressure, particularly if used in combination with atropine.

3.9 Administration routes and dosage

For oral use.

Each depression of the pump delivers 4 ml of product (0.100 mg of clenbuterol hydrochloride, equivalent to 0.088 mg clenbuterol).

The pump needs to be primed before the first use only. Prime the pump by pressing twice and discard the retrieved syrup.
It is not possible to extract all the contents using the pump provided.

Administer 4 ml of the product per 125 kg bodyweight twice daily.
This is equivalent to twice daily administration of 0.8 micrograms clenbuterol hydrochloride per kg bodyweight.

The syrup should be added to the feed.

Treatment should continue for as long as necessary.

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

Dosages of clenbuterol hydrochloride up to 4 times the therapeutic dose (administered orally) for a period of 90 days caused transient side effects typical for beta2-adrenoceptor agonists (sweating, tachycardia, muscle tremor), which required no treatment.

In case of accidental overdose, a β-blocker (such as propranolol) may be used as 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

3.12 Withdrawal periods

Meat and offal:28 days
Not authorised for use in lactating animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QR03CC13

4.2 Pharmacodynamics

The product contains clenbuterol hydrochloride, which is a sympathomimetic amine which preferentially binds to β2 adrenoreceptors on cell membranes of the bronchi.

This subsequently activates the enzyme adenylate cyclase in smooth muscle cells, thus providing intense bronchodilating properties and decreasing airway resistance with minimum effect on the cardiovascular system. The product has been shown to inhibit histamine release from mast cells in the lungs and enhance mucociliary clearance in horses.

4.3 Pharmacokinetics

After oral administration in horses, clenbuterol is readily absorbed and maximum plasma concentrations reached within 2 hours of dosing. Steady state concentrations in plasma are reached after 3-5 days treatment and range from 1.0 – 2.2 ng/ml.

The substance is rapidly distributed in tissues and metabolised primarily by the liver. Clenbuterol is the main excretory product and approximately 45% of the dose is eliminated unchanged in the urine. The kidneys excrete 70 – 91% of the total dose, and the remainder is eliminated in the faeces (6 – 15%).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 3 months

5.3 Special precautions for storage

Do not store above 25°C. Protect from light.

5.4 Nature and composition of immediate packaging

355 ml HDPE bottle sealed with an aluminium/PE heat seal or a transparent HDPE cap. The product is supplied in a carton box with a multi-component mechanical pump dispenser capable of delivering 4 ml of the product.

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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 41821/3003

8. DATE OF FIRST AUTHORISATION

07 March 2013

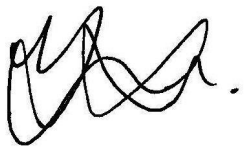
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2023

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).



Approved: 22 March 2024