ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dilaterol 25 micrograms/ml syrup

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Clenbuterol hydrochloride 25 micrograms
(corresponding to 22 microgramsclenbuterol)

3. PACKAGE SIZE

355 ml bottle with pump dispenser

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use, administered with feed.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within: 3 months.
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

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

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

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/3003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dilaterol 25 micrograms/ml syrup -

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Clenbuterol hydrochloride 25 micrograms
(corresponding to 22 micrograms clenbuterol)

3. TARGET SPECIES

Horses.

4. ROUTES OF ADMINISTRATION

For oral use, administered with feed.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within: 3 months.
Once opened, use by…

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Vm 41821/3003

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dilaterol 25 micrograms/ml syrup for horses.

2. Composition

Each ml contains:

Active substance
Clenbuterol hydrochloride 25 micrograms
(corresponding to 22 micrograms clenbuterol)

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

Clear colourless syrup

3. Target species

Horses.

4. Indications 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. To be used alone or as adjuvant therapy.

5. 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 6.

6. Special warnings

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.

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.

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.

Overdose:
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.

Special restrictions for use and special conditions for use:

Major incompatibilities:
None known.

7. Adverse events

Rare (1 to 10 animals / 10,000 animals treated):	Restlessness; Tachycardia (rapid heart rate), Hypotension (low blood pressure)[a]; Muscle tremor; Hyperhidrosis (excessive sweating)[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 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 the local representative of the marketing authorisation holder> 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 oral use.

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.

9. Advice on correct administration

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.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C. Protect from light.
Do not use this veterinary medicineal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 3 months

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

Vm 41821/3003

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.

15. Date on which the package leaflet was last revised

October 2023

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

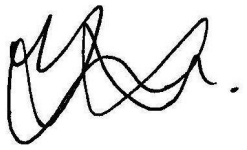
16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4841 SJ Raamsdonksveer
The Netherlands

<Local representatives and contact details to report suspected adverse reactions:>

17. Other information



Approved: 22 March 2024