ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventiquin 25 microgram/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Clenbuterol hydrochloride 25 microgram/ml
(equivalent to 22 microgram/ml clenbuterol)

3. PACKAGE SIZE

360 ml and a syringe

4. TARGET SPECIES

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
After first opening the immediate packaging do not store above 25°C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Pregnant women should take care when handling the veterinary medicinal product.
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

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3052

15. BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

Plastic (HDPE) bottle

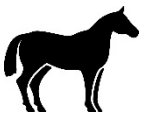
1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventiquin 25 microgram/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Clenbuterol hydrochloride 25 microgram/ml
(equivalent to 22 microgram/ml clenbuterol)

3. TARGET SPECIES



4. ROUTES OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.
After first opening the immediate packaging do not store above 25°C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

9. BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ventiquin 25 microgram/ml oral solution for horses

2. Composition

Each ml contains:

Active substances:
Clenbuterol hydrochloride 25 microgram
(equivalent to 22 microgram clenbuterol)

Excipients:
Methyl parahydroxybenzoate (E218) 1.8 mg
Propyl parahydroxybenzoate 0.2 mg

Slightly viscous, colourless to slightly yellow solution.

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.

5. Contraindications

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

6. Special warnings

Special warnings:
None

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.
Dermal exposure and accidental ingestion, including hand-to-mouth contact should be avoided. When using this veterinary medicinal product do not eat, drink or smoke to avoid accidental intake of the veterinary medicinal product.
To avoid accidental ingestion by or exposure to a child, do not leave the filled syringe unattended and close the bottle immediately and properly after use.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.
This veterinary medicinal product may cause embryotoxicity. Pregnant women should take care when handling the veterinary medicinal product. Wear gloves to avoid skin contact.
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to any of the excipients (parabens, polyethylene glycol and/or triethanolamine) should avoid exposure to the veterinary medicinal product. In case of hypersensitivity reactions or if irritation persists, seek medical advice and show the package leaflet or label to the physician.
This veterinary medicinal product may be irritating to the skin and/or eyes. Avoid skin and/or eye contact. In case of accidental skin contact, wash skin thoroughly. In case of accidental eye contact, flush thoroughly with clean water.

Pregnancy:
If used during pregnancy, treatment must be discontinued a minimum of 4 days before the expected time of delivery or at signs of approaching parturition if the expected date of delivery is unknown or unscheduled., since uterine contractions may be abolished or labour may be prolonged.

Lactation:
Avoid administration to nursing mares because of excretion in the milk. 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:
Effects including side effects may be enhanced with simultaneous use with glucocorticoids, ß2-sympathomimetics, anticholinergics and methylxanthines.
The veterinary medicinal product should not be used concomitantly with other sympathomimetics or vasodilators.
In animals treated with clenbuterol disturbances of the heart rhythm can be expected upon anaesthesia.
Simultaneous administration of narcotics containing halogens (isoflurane, methoxyflurane) increases the risk of ventricular arrhythmias.
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.
Increased risk of arrhythmia with simultaneous administration of digitalis glycosides.
The veterinary medicinal product can reduce or neutralise the effects of prostaglandin F2α and oxytocin on the uterus.

Clenbuterol hydrochloride is a β -adrenergic agonist and is subsequently neutralised by β-blockers.

Overdose:
Doses of clenbuterol hydrochloride up to 4 times the therapeutic dose (orally administered) administered for 90 days caused only temporary side effects typical for $ß_2$-adrenoceptor agonists (sweating, tachycardia, muscle tremor) which did not require treatment.
In case of accidental overdose, a ß -blocker (such as propranolol) may be used as antidote.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Tachycardia[1]; hypotension[1]; Lethargy[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Increased sweating[1]; Nervousness[1]

[1] Transient.

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:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Oral use.

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

Administer 0.8 micrograms clenbuterol hydrochloride per kilogram body weight (i.e. 0.7 micrograms clenbuterol per kg bodyweight), corresponding to 4 ml oral solution / 125 kg body weight, twice daily, with approximately 12 hours (minimum 8 hours) apart.

The duration of the treatment is a maximum of ten consecutive days.
This veterinary medicinal product is intended for individual animal treatment.

9. Advice on correct administration

The veterinary medicinal product is administered with a small quantity of food.
Use the supplied syringe for measuring the dose to be delivered. Place the syringe nozzle into the opening of the bottle and withdraw the necessary volume.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 °C.
After first opening the immediate packaging do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp..
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

White HDPE bottle with white polypropylene child-resistant screw cap and LDPE syringe inlay.

The veterinary medicinal product is supplied in a cardboard box with a measuring device, a 25 ml syringe with polypropylene body and polyethylene plunger. The syringes are graduated per 1 ml.

Each bottle contains 360 ml.

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15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel.: +31 348 416945

Manufacturer responsible for batch release:
Floris Veterinaire Produkten B.V.
Kempenlandstraat 33
5262 GK Vught
The Netherlands

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 19 August 2026