PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Syrup 25 micrograms/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition:
1 ml Ventipulmin® Syrup contains 25 micrograms clenbuterol hydrochloride plus 1.8 mg methyl parahydroxybenzoate E218 and 0.2 mg propyl parahydroxybenzoate E214 as preservatives.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

355 ml

5. TARGET SPECIES

6. INDICATION(S)

Indications:
Treatment of respiratory disease in horses where 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. (See package leaflet).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration and Dosage:
For oral use. One complete depression of plunger delivers 4 ml syrup. Add 4 ml of syrup per 125 kg body weight to feed, twice daily. Thus, an adult horse weighing 500 kg (approx. 1000 lbs) should receive 16 ml of syrup i.e. 4 complete depressions of the plunger, twice daily.

8. WITHDRAWAL PERIOD

Withdrawal periods:
Horses intended for human consumption should not be slaughtered until 28 days after treatment.
Do not use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Warnings:
Ventipulmin® antagonises the effects of prostaglandin F2 alpha and oxytocin. Ventipulmin® is antagonised by beta-adrenergic blocking agents. If used during pregnancy, treatment must be discontinued at the expected time of delivery since

uterine contractions may be abolished under its influence. This product contains clenbuterol, a beta-agonist. Take care to avoid skin contact. In case of skin contact wash affected area thoroughly. If irritation occurs/persists seek medical advice. Take care to avoid accidental eye contact. In the case of accidental eye contact, flush thoroughly with clean water and seek medical advice. When using do not eat, drink or smoke. Wash hands thoroughly after using the product. For further contra-indications and warnings, see package leaflet.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Keep bottle in outer carton.
This pack should be used within 30 days of first opening. Discard unused material.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
To be used in accordance with the directions of a veterinary surgeon.

UK : VM 08327/4310 : POM-V : To be supplied only on veterinary prescription.

IE: VPA 10007/12/1 : POM : Prescription Only Medicine

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4310
VPA 10007/12/1

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. OTHER INFORMATION

Veterinary Bronchodilator

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Syrup 25 micrograms/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Composition: 1 ml Ventipulmin® Syrup contains 25 micrograms clenbuterol hydrochloride plus 1.8 mg methyl parahydroxybenzoate E218 and 0.2 mg propylhydroxybenzoate E214 as preservatives.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

355 ml

4. ROUTE(S) OF ADMINISTRATION

Administration and Dosage: For oral use. One complete depression of plunger delivers 4 ml syrup. Add 4 ml of syrup per 125 kg body weight to feed, twice daily. Thus, an adult horse weighing 500 kg (approx. 1000 lbs) should receive 16 ml of syrup i.e. 4 complete depressions of the plunger, twice daily.

5. WITHDRAWAL PERIOD

Withdrawal periods: Horses intended for human consumption should not be slaughtered until 28 days after treatment.
Do not use in animals producing milk for human consumption.

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry Date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. OTHER INFORMATION

Indications: Treatment of respiratory disease in horses where 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.
(See package leaflet).
Warnings: Ventipulmin® antagonises the effects of prostaglandin F2 alpha and oxytocin.

Ventipulmin® is antagonised by betaadrenergic blocking agents. If used during pregnancy, treatment must be discontinued at the expected time of delivery since uterine contractions may be abolished under its influence.
This product contains clenbuterol, a beta-agonist. Take care to avoid skin contact. In case of skin contact wash affected area thoroughly. If irritation occurs/persists seek medical advice. Take care to avoid accidental eye contact. In case of accidental eye contact, flush thoroughly with clean water and seek medical advice. When using do not eat, drink or smoke. Wash hands thoroughly after using the product.
For further contra-indications and warnings, see package leaflet.

Do not store above 25°C. Protect from light. This pack should be used within 30 days of first opening. Discard unused material. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Keep out of reach and sight of children.

Keep bottle in outer carton.

To be used in accordance with the directions of a veterinary surgeon. To be supplied only on veterinary prescription.

UK : VM 08327/4310 : POM-V
IE : VPA 10007/12/1 : POM

Marketing Authorisation Holder
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Veterinary bronchodilator

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR: Ventipulmin Syrup 25 micrograms/ml Clenbuterol hydrochloride

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorization holder
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer for batch release:
Boehringer Ingelheim Vetmedica GmbH,
D 55216, Ingelheim am/Rhein,
Germany.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin syrup 25 micrograms/ml

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Presentation:
A clear colourless syrup. Each ml contains 25 micrograms clenbuterol hydrochloride plus 1.8 mg methylparahydroxybenzoate E218 and 0.2 mg propyl parahydroxybenzoate E214 as preservatives.

4. INDICATION(S)

Uses:
Treatment of respiratory disease in horses where 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. In cases accompanied by bacterial infection the administration of antimicrobial agents is recommended.
In particular:
1. Acute, sub-acute and chronic infections where the presence of mucus and/or micro-organisms may stimulate bronchospasm or cause airway obstruction and thus increase airway resistance. For example, bronchitis, bronchiolitis and bronchopneumonia alone or associated with equine influenza and other viral respiratory diseases.
2. Acute, sub-acute and chronic respiratory allergies.
3. Chronic obstructive pulmonary disease (COPD) in horses.

5. CONTRAINDICATIONS

Contra-indications, warnings etc:
Do not use in cases of known hypersensitivity to clenbuterol. Do not use in horses with known cardiac disease.

Ventipulmin® antagonises the effects of prostaglandin F2-alpha and oxytocin and is antagonised by β-adrenergic blocking agents.

In case of accidental overdose, a β− blocker such as propranolol may be used as an antidote.

If used during pregnancy, treatment must be discontinued at the expected time of delivery since uterine contractions may be abolished under its influence.

6. ADVERSE REACTIONS

Adverse effects
Clenbuterol may cause side-effects such as sweating (mainly neck region), muscle tremor, tachycardia, slight hypotension or restlessness. These are typical for β-agonists and occur rarely. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and Administration:
For oral use.
Dosage: Twice daily administration of 0.8 micrograms of clenbuterol hydrochloride per kg bodyweight. This corresponds to a twice daily administration of 4ml of the syrup per 125kg bodyweight. (One depression of the pump delivers 4 ml syrup). The syrup should be added to the feed. Treatment should be continued for as long as necessary. To be supplied only on veterinary prescription.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Withdrawal Periods
Horses intended for human consumption should not be slaughtered until 28 days after treatment.

Do not use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical Precautions:
Do not store above 25°C. Protect from light.

This pack should be used within 30 days of opening. Discard unused material. Do not use after the expiry date stated on the label and carton.

12. SPECIAL WARNING(S)

User precautions
This product contains clenbuterol, a β-agonist. Take care to avoid skin contact. In case of skin contact wash affected area thoroughly. If irritation occurs/persists seek medical advice. Take care to avoid accidental eye contact. In case of accidental eye contact, flush thoroughly with clean water and seek medical advice. When using do not eat, drink or smoke. Wash hands thoroughly after using the product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal Advice:
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Veterinary Bronchodilator

Package Quantities:
Screw top polyethylene bottle containing 355 ml syrup with 4 ml pump dispenser.

Marketing Authorisation Numbers

UK : VM 08327/4310 : POM-V :
To be supplied only on veterinary prescription.

IE: VPA 10007/12/1 : POM :
Prescription Only Medicine

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Approved 09 November 2018