

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Solution for Injection 30 micrograms/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition

Solution for injection. Each ml contains 30 micrograms clenbuterol hydrochloride and 10 mg benzyl alcohol (preservative E1519).

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

6. INDICATION(S)

Indications

Treatment of obstructive respiratory disease in horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration

2.7 ml/100 kg bodyweight twice daily by slow intravenous injection.

8. WITHDRAWAL PERIOD

Withdrawal period

Horse meat: 28 days.

Do not use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User precautions : 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.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Keep container in outer carton. Do not use after the stated expiry date.

Once broached, use by:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

For animal treatment only.

UK : VM 08327/4309 : POM-V : To be supplied only on veterinary prescription.
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IE : VPA 10007/11/2 : POM : Prescription Only Medicine
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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 08327/4309
VPA 10007/11/2

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. OTHER INFORMATION

See package leaflet for full details of uses, dosage, contra-indications and warnings.

MINIMUM PARTICULARS TO APPEAR ON THE SMAL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Solution for Injection 30 micrograms/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Composition: Solution for injection. Each ml contains 30 micrograms clenbuterol hydrochloride and 10 mg benzyl alcohol (preservative, E1519).

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Dosage and Administration: 2.7 ml/100 kg bodyweight twice daily by slow intravenous injection.

5. WITHDRAWAL PERIOD

Withdrawal period

Horse meat: 28 days.

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 obstructive respiratory disease in horses.

See package leaflet for full details of uses, dosage, contraindications and warnings.

Do not store above 25°C. Do not use after the stated expiry date. Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Keep container in outer carton.

Keep out of reach and sight of children.

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

User precautions: 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.

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

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

PACKAGE LEAFLET FOR: Ventipulmin Solution for Injection 30 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:

Labiana Life Sciences S.A.

E – 08228 Barcelona

Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Solution for Injection 30 micrograms/ml

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

Presentation

A clear colourless aqueous solution for injection.

Each ml contains 30 micrograms clenbuterol hydrochloride and 10 mg benzyl alcohol (preservative, E1519).

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 or cardiac disease.

Ventipulmin® Injection solution antagonises the effects of prostaglandin F_{2-α} 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. These effects can be minimised when using the injection by administering it slowly. 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

Dosage: For slow intravenous administration. Twice daily administration of 0.8 micrograms of clenbuterol hydrochloride per kg bodyweight. This dose corresponds to a twice daily administration of 2.7 ml of the injection per 100 kg bodyweight. Treatment should be continued for as long as necessary.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Withdrawal Periods

Horses intended for human consumption should not be slaughtered for human consumption 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. Following withdrawal of the first dose, use the product within 28 days. When the container is broached for the first time, using this in-use shelflife which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written on the space provided on the carton. Discard unused material. Keep container in outer carton. Do not use after the stated expiry date.

12. SPECIAL WARNING(S)

User precautions: 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.

Accidental self-injection of Ventipulmin® Injection solution may produce tachycardia and tremor. These effects may be reversed by the use of a non-selective β -blocker. If accidental self-injection occurs seek medical advice immediately avoiding driving if possible.

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

To be supplied only on veterinary prescription.

Package Quantities

Amber glass injection vial containing 50 ml of solution.

Marketing Authorisation Numbers

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FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.



Approved 09 November 2018