SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Solution for Injection 30 micrograms/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Clenbuterol hydrochloride 30 micrograms
Preservative:
Benzyl alcohol 10 mg/ml

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the 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 muco-ciliary clearance is desirable. To be used alone or as adjuvant therapy.

In particular:
i) Acute, sub-acute and chronic respiratory allergies.
ii) Acute, sub-acute and chronic infections where the presence of mucu and/or micro-organisms may stimulate bronchospasm or cause airway obstruction and thus an increase in airway resistance. For example; bronchitis, bronchiolitis and bronchopneumonia alone, or associated with equine influenza and other viral respiratory diseases.
iii) Chronic Obstructive Pulmonary Disease (COPD).

In cases accompanied by bacterial infection the administration of antimicrobial agents is recommended.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

Do not use in horses with known cardiac disease.

4.5 Special precautions for use

Do not use in cases of known hypersensitivity to clenbuterol

i) Special precautions for use in animals

None known.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals.

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 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.

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

4.6 Adverse reactions (frequency and seriousness)

In clinical use, it has been noted that following intravenous administration to horses, cases of transient mild muscle tremor and sweating were observed. It is suggested that a ‘bolus’ effect may have occurred in these cases and caused transient peripheral vasodilation. This vasodilation is a feature exhibited by all beta-adrenergic drugs to a greater or lesser degree. These effects may be minimised by administering the product slowly.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

This product antagonises the effects of prostaglandin F_2-alpha and oxytocin.
This product is antagonised by β-adrenergic blocking agents.

4.9 Amounts to be administered and administration route

Administer by slow intravenous injection at a dose of 2.7 ml per 100 kg bodyweight twice daily for as long as necessary. This is equivalent to twice daily administration of 0.8 micrograms clenbuterol hydrochloride per kg bodyweight.

Avoid the introduction of contamination during use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

See Section 4.6 for likely clinical effects. In case of accidental overdose, a β-blocker such as propanolol may be used.

4.11 Withdrawal period

Meat and offal: 28 days
Do not use in animals producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QR03CC13

The product contains the active ingredient clenbuterol hydrochloride, which is a sympathomimetic amine with a high degree of selectivity for the β_2-receptor sites in the body, thus providing intense bronchodilating properties with minimum effect on the cardiovascular system. It has been shown to stimulate muco-ciliary clearance in horses.

The effects on pulmonary function and clinical response have been assessed in clinical trials with horses suffering from a variety of respiratory conditions.

A marked decrease in intrathoracic pressure, a decrease in respiratory rate, an initial decrease followed by an increase in arterial oxygen partial pressure and clinical improvements were observed. In addition, a significant reduction in resistance to airflow and a clinical improvement in the animals respiratory pattern were seen.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Sodium Chloride
Hydrochloric Acid (Dilute) (for pH adjustment)
Water for Injections.

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the medicinal product as packaged for sale**:** 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
Should any growth or discolouration occur, the product should be discarded.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

50 ml amber glass injection vial (Ph Eur. Type II), with pink bromobutyl rubber stopper and aluminium crimp cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products.

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4309

9. DATE OF FIRST AUTHORISATION

22 August 1994

10. DATE OF REVISION OF THE TEXT

November 2018

Approved 09 November 2018