SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Granules 16 micrograms/gram

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains

Active substance:
Clenbuterol hydrochloride 16 micrograms

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules.
White, finely grained free flowing granules.

4. CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

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 particular :

i) Acute, sub-acute and chronic infections where the presence of mucus 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.
ii) Acute, sub-acute and chronic respiratory allergies.
iii) Chronic Obstructive Pulmonary Disease (COPD) in horses.

In cases complicated by the presence of micro-organisms the simultaneous use of antimicrobial agents is indicated.

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

Not applicable.

(i) Special precautions for use in animals
Do not use in animals with known hypersensitivity to the active substance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals.
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. Avoid inhaling dust.

4.6 Adverse reactions (frequency and seriousness)

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.

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

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

4.9 Amounts to be administered and administration route

For oral administration.
Twice daily administration of 0.8 micrograms clenbuterol per kg bodyweight, for as long as necessary. This is equivalent to twice daily administration of 5g granules per 100kg bodyweight.

The granules should be added to the feed.
Add to feed immediately before administration. Discard any remaining medicated feed.

A measuring scoop is provided with the 500g pack. When full, the scoop contains 10g. A second line on the scoop indicates a half measure (5g).

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

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.

4.11 Withdrawal period(s)

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 B_2-receptor sites in the body, thus providing intense bronchodilating properties with minimum effect on the cardiovascular system. It has been shown to stimulate mucociliary 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.

The active substance is well absorbed following oral administration. Oral and parenteral dose rates are identical at 0.08 micrograms per kg bodyweight.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Lactose Monohydrate
Maize Starch, Dried
Povidone
Maize Starch, Soluble

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the medicinal product as packaged for sale**:** 3 years.

6.4 Special precautions for storage

Do not store above 30°C. Protect from light. Discard unused material.
Add to feed immediately before administration.
Discard remaining medicated feed.

6.5 Nature and composition of immediate packaging

The product is packed in a polyethylene container with a push-fit polyethylene cap. The container is filled with 500 g granules. A polystyrene measuring spoon, graduated at 5g and 10g is also supplied.

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 08327/4308

9. DATE OF FIRST AUTHORISATION

22 August 1994

10. DATE OF REVISION OF THE TEXT

November 2018

Approved 09 November 2018