

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Syrup 25 micrograms/ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Clenbuterol hydrochloride 25 micrograms

Excipients:

Methyl parahydroxybenzoate 1.8 mg

Propyl parahydroxybenzoate 0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

Clear colourless syrup.

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 mucociliary 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 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.
- iii) Chronic Obstructive Pulmonary Disease (COPD).

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

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.
Do not use in horses with known cardiac disease.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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.

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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 F₂ -alpha and oxytocin.
Ventipulmin is antagonised by β -adrenergic blocking agents.

4.9 Amounts to be administered and administration route

For oral use.

Administer 4 ml Ventipulmin Syrup per 125 kg bodyweight twice daily.

This is equivalent to twice daily administration of 0.8 micrograms clenbuterol hydrochloride per kg bodyweight.

The syrup should be added to the feed. (One depression of the pump delivers 4 ml syrup).

Treatment should continue for as long as necessary.

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

Pharmacotherapeutic group: Adrenergics for systemic use (selective beta2-adrenoreceptor agonists)

ATC Vet code : QR03CC13: Drugs for obstructive airway disease.

5.1 Pharmacodynamic properties

Ventipulmin contains clenbuterol hydrochloride, which is a sympathomimetic amine which preferentially binds to β_2 adrenoreceptors on cell membranes of the bronchi. This subsequently activates the enzyme adenylate cyclase in smooth muscle cells, thus providing intense bronchodilating properties and decreasing airway resistance with minimum effect on the cardiovascular system. Ventipulmin has been shown to inhibit histamine release from mast cells in the lungs, and enhance mucociliary clearance in horses.

5.2 Pharmacokinetic particulars

After oral administration in horses, clenbuterol is readily absorbed and maximum plasma concentrations reached within 2 hours of dosing. Steady state level in plasma is reached after 3-5 days treatment and range from 1.0 – 2.2 ng/ml.

The substance is rapidly distributed in tissues and metabolised primarily by the liver. Clenbuterol is the main excretory product and approximately 45% of the dose is eliminated unchanged in the urine. The kidneys excrete 70 – 91% of the total dose, and the remainder is eliminated in the faeces (6 – 15%).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Carbomer 934P
Sucrose
Macrogol 400
Glycerol
Ethanol
Trolamine
Water, purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 30 days.

6.4. Special precautions for storage

Do not store above 25°C.
Protect from light.
Keep the bottle in the outer carton.

6.5 Nature and composition of immediate packaging

355 ml screw top polyethylene bottle with a 4 ml pump dispenser.

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 materials derived from such veterinary medicinal product 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 NUMBERS

Vm 08327/4310

9. DATE OF FIRST AUTHORISATION

29 January 1991

10. DATE OF REVISION OF THE TEXT

November 2018

A handwritten signature in black ink, consisting of several vertical strokes followed by a long, sweeping horizontal stroke that curves upwards at the end.

Approved 09 November 2018