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 hydrochloride16 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 accompanied 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
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product contains clenbuterol, a beta agonist. Take case to avoid skin contact. In case of skin contact, wash affected area thoroughly. If irritation occurs/persists seek medical advice. Take case 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. After use, wash any contaminated skin immediately with soap and clean water. 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 beta-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 interactions

Ventipulmin antagonises the effects of prostaglandin F_2-alpha and oxytocin.

Ventipulmin is antagonised by beta-adrenergic blocking agents.

4.9 Amounts to be administered and administration route

For oral use.
Administer 5g Ventipulmin Granules per 100 kg bodyweight twice daily. This is equivalent to twice daily administration of 0.8 micrograms clenbuterol per kg bodyweight.

The granules should be added to the feed.
Treatment should continue for as long as necessary.

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

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

Dosages up to 4 times the therapeutic dose (administered orally) for a period of 90 days caused transient adverse reactions 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 or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ventipulmin contains clenbuterol hydrochloride, which is a sympathomimetic amine which preferentially binds to $beta_2$ 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 are 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

Mannitol
Lactose
Maize starch
Povidone
Soluble starch

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Add to feed immediately before administration. Discard remaining medicated feed

6.4 Special precautions for storage

Do not store above 30°C.
Protect from light

6.5 Nature and composition of immediate packaging

The product is packed in a polyethylene container with a push-fit polyethylene cap and a measuring spoon (10 g granules). The container is filled with 500 g granules.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

November 2018