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:

Qualitative composition of excipients and other constituents
Mannitol
Lactose
Maize Starch
Povidone
Soluble Starch

White, finely grained free flowing granules.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses with known cardiac disease.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal 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 and show the package leaflet or label to the physician. When using do not eat, drink or smoke. After use, wash any contaminated skin immediately with soap and clean water. Avoid inhaling dust.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Rare (1 to 10 animals / 10 000 animals treated):	Restlessness[1],Hypotension[1,2], Tachycardia[1], Muscle tremor[1], Increased sweating[1, 3]

[1]Typical for beta-agonists.
[2]Slight.
[3]Mainly neck region.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product antagonises the effects of prostaglandin F_2 -alpha and oxytocin. Ventipulmin is antagonised by beta-adrenergic blocking agents.

3.9 Administration routes and dosage

For oral use.
Administer 5 g of the veterinary medicinal product 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 provided with the 500 g pack contains 10 g when full. A scored line on the scoop indicates a half measure (5 g).

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

4.1 ATCvet code :

QR03CC13

4.2 Pharmacodynamics

The veterinary medicinal product 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. The veterinary medicinal product has been shown to inhibit histamine release from mast cells in the lungs, and enhance mucociliary clearance in horses.

4.3 Pharmacokinetics

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%).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 30 °C.
Protect from light.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is packed in a high density polyethylene container with a push-fit low density polyethylene cap and a polystyrene measuring spoon (10 g granules). The container is filled with 500 g granules.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10454/018/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

31/07/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).