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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate (E214)	0.2 mg
Carbomer 934P	
Sucrose	
Macrogol 400	
Glycerol	
Ethanol	
Trolamine	
Purified water	

Clear colourless syrup.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each 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 diseases.
iii) Chronic Obstructive Pulmonary Disease (COPD).

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 substances 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 hydrochloride, a beta-agonist.
Take care to avoid skin contact. In case of accidental skin contact, wash affected area thoroughly. If irritation occurs/persists seek medical advice and show the package leaflet or the label to the physician.
Take care to avoid eye contact. In the case of accidental eye contact, flush thoroughly with clean water and seek medical advice and show the package leaflet or the label to the physician.
Do not eat, drink or smoke when using the veterinary medicinal product. Wash hands thoroughly after using the veterinary medicinal product.
People with known hypersensitivity to clenbuterol should avoid contact with the veterinary medicinal product.

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 prostglandin F_2-alpha and oxytocin.
The veterinary medicinal product is antagonised by beta-adrenergic blocking agents.

3.9 Administration routes and dosage

For oral use.
Administer 4 ml of the veterinary medicinal product per 125 kg bodyweight twice daily.
This is equivalent to twice daily administration of 0.8 micrograms of 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.

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 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 levels in plasma is reached after 3-5 days treatment and ranges 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: 2 years.
Shelf life after first opening the immediate packaging: 30 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

355 ml screw top polythene bottle with a 4 ml pump dispenser.
Pack size:
Cardboard box containing 1 bottle of 355 ml.

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)

VPA10454/020/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

29/07/2026

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).