

## **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  $\beta$ -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 interaction**

Ventipulmin antagonises the effects of prostaglandin F<sub>2</sub>-alpha and oxytocin. Ventipulmin is antagonised by  $\beta$ -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  $\beta$ -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<sub>2</sub>-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**

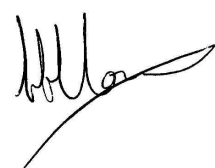
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## **9. DATE OF FIRST AUTHORISATION**

22 August 1994

## **10. DATE OF REVISION OF THE TEXT**

November 2018



Approved 09 November 2018