

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipulmin 25 micrograms/ml syrup for horses.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

#### Active substance

Clenbuterol hydrochloride 25 micrograms

(corresponding to 22 micrograms clenbuterol)

#### Preservatives:

Methyl parahydroxybenzoate (E218) 2.02 mg

Propyl parahydroxybenzoate 0.26 mg

For a 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 mucous is a contributing factor, and improved mucociliary clearance is desirable. To be used alone or as adjuvant therapy.

#### 4.3 Contraindications

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

Do not use in horses with known cardiac disease.

For use during pregnancy or lactation see section 4.7.

#### 4.4 Special warnings for each target species

None.

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

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

In case of glaucoma the product must only be used after a careful risk-benefit assessment.

Special precautions should be taken in case of halothane anaesthesia, since the heart function can show increased sensitivity to catecholamines.

### **Special precautions to be taken by the person administering the medicinal product to animals**

This product contains clenbuterol hydrochloride, a beta-agonist.

Wear gloves to avoid skin contact. In case of accidental skin contact, wash affected area thoroughly. If irritation occurs/persists seek medical advice. Wash hands thoroughly after using the product.

Take care to avoid eye contact. In the case of accidental eye contact, flush thoroughly with clean water and seek medical advice.

Do not eat, drink or smoke when using this product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the healthcare professional.

People with known hypersensitivity to clenbuterol should avoid contact with the veterinary medicinal 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  $\beta$ -agonists and occur rarely.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## **4.7 Use during pregnancy, lactation or lay**

If used during pregnancy, treatment must be discontinued a minimum of 4 days before the expected time of delivery, since uterine contractions may be abolished or labour may be prolonged under its influence.

## **4.8 Interaction with other medicinal products and other forms of interaction**

The product antagonises the effects of prostaglandin F<sub>2</sub>-alpha and oxytocin.

The product is antagonised by  $\beta$ -adrenergic blocking agents.

Do not administer concurrently with other beta-adrenergic agents.

During the use of both local and general anaesthetics one cannot exclude a further vascular dilatation and fall of blood pressure, particularly if used in combination with atropine.

## 4.9 Amounts to be administered and administration route

For oral use.

Each depression of the pump delivers 4 ml of product (0.100 mg of clenbuterol hydrochloride, equivalent to 0.088 mg clenbuterol).

The pump needs to be primed before the first use only. Prime the pump by pressing twice and discard the retrieved syrup.

It is not possible to extract all the contents using the pump provided.

Administer 4 ml of the product 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.

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  $\beta$ -blocker (such as propranolol) may be used as antidote.

## 4.11 Withdrawal Period(s)

Meat and offal – 28 days

Not authorised for use in lactating animals producing milk for human consumption.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: selective beta-2-adrenoreceptor agonists

ATC Vet code : QR03CC13

### 5.1 Pharmacodynamic properties

The 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 adenylyl cyclase in smooth muscle cells, thus providing intense bronchodilating properties and decreasing airway resistance with minimum effect on the cardiovascular system. The product has been shown to inhibit histamine release from mast cells in the lungs, and enhance mucociliary clearance in horses.

### 5.2 Pharmacokinetic properties

After oral administration in horses, clenbuterol is readily absorbed and maximum plasma concentrations reached within 2 hours of dosing. Steady state concentrations 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**

Methyl parahydroxybenzoate (E218)  
Propyl parahydroxybenzoate  
Sucrose  
Carbomer 974P

Macrogol 400  
Glycerol (85%)  
Ethanol (96%)  
Sodium hydroxide  
Water, purified

### **6.2 Incompatibilities**

Not known.

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years  
Shelf life after first opening the immediate packaging : 3 months

### **6.4 Special precautions for storage**

Do not store above 25°C. Protect from light.

### **6.5 Nature and composition of immediate packaging**

335 ml HDPE bottle sealed with an aluminium/PE heat seal and a transparent HDPE cap. The product is supplied in a carton box with a multi-component mechanical pump dispenser capable of delivering 4 ml of the product.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Reveta GmbH  
Ostlandring 13  
31303 Burhdorf  
Germany

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA: 10467/001/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

11th January 2013

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

