

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 the 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 mucus 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 veterinary 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 β -agonists and occur rarely.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy or lactation

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.

Since clenbuterol hydrochloride is excreted in milk, the product should not be used in lactating mares with foals up to the age of two months.

4.8 Interaction with other medicinal products and other forms of interaction

The product antagonises the effects of prostaglandin F₂-alpha and oxytocin.

The product is antagonised by β -adrenergic blocking agents.

Enhanced effects including more frequent adverse effects when used concomitantly with β_2 sympathomimetic drugs, anticholinergic substances, and methylxanthines.

Increased risk of arrhythmias when administered concomitantly with digitalis glycosides.

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 (0.7 micrograms clenbuterol per kg bodyweight).

The syrup should be added to the feed.

Duration of treatment: 10-14 days in acute or subacute conditions, over a longer period of time in chronic cases. If signs improve significantly, the dosage can be reduced by half after approximately 10 days.

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 β -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 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 β_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 product 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 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 Major 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

355 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 product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burhdorf
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 20916/4024

9. DATE OF FIRST AUTHORISATION

18 December 2012

10. DATE OF REVISION OF THE TEXT

November 2021

Revised: November 2021
AN: 00701/2021 and 00702/2021

Approved: 17/11/21

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending to the right from the end of the name.