1. Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipulmin 25 micrograms/ml syrup for horses.
Clenbuterol hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Clenbuterol hydrochloride 25 micrograms
(corresponding to 22 micrograms clenbuterol)

Preservatives:
Methyl parahydroxybenzoate (E218) 2.02 mg
Propyl parahydroxybenzoate 0.26 mg

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

355 ml bottle with pump dispenser

5. TARGET SPECIES

Horse

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use, administered with feed.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 3 months.
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20916/4024

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
PE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipulmin 25 micrograms/ml syrup for horses.
Clenbuterol hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Clenbuterol hydrochloride 25 micrograms
(corresponding to 22 micrograms clenbuterol)

Preservatives:
Methyl parahydroxybenzoate (E218) 2.02 mg
Propyl parahydroxybenzoate 0.26 mg

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

355 ml bottle with pump dispenser

5. TARGET SPECIES

Horse

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use, administered with feed.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 3 months.
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20916/4024

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

PACKAGE LEAFLET

Equipulmin 25 micrograms/ml syrup for horses.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipulmin 25 micrograms/ml syrup for horses.
Clenbuterol-hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

Clear colourless syrup.

4. INDICATION(S)

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.

5. 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 12.

6. ADVERSE REACTIONS

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)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

For animal treatment only. For oral use administered with feed

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species

None

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.

Pregnancy and 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.

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 ß2 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.

Overdose (symptoms, emergency procedures, antidotes)

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.

Incompatibilities
Not known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2021

15. Other information

Carton box with 355 ml HDPE bottle sealed with an aluminium/PE heat seal and a transparent HDPE cap packed together with a multi-component mechanical pump dispenser.

Approved: 17/11/21