MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

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

Marketing Authorisation Holder

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer

Klocke Pharma Service GmbH
D-77767 Appenweier, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ventipulmin Granules 16 micrograms/gram

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

1 g Ventipulmin granules contains 16 micrograms of clenbuterol hydrochloride.

4. PHARMACEUTICAL FORM

Granules.

White finely grained free-flowing granulate with a hardly perceptible odour.

5. PACKAGE SIZE

500 g

6. INDICATION(S)

Uses

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

1. Acute, sub-acute and chronic infections where the presence of mucus and/or microorganisms may stimulate bronchospasm or cause airway obstruction and thus increase airway resistance. For example, bronchitis, bronchiolitis and bronchopneumonia alone or associated with equine influenza and other viral respiratory diseases.
2. Acute, sub-acute and chronic respiratory allergies.
3. Chronic obstructive pulmonary disease (COPD) in horses.

7. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active ingredient or cardiac disease. This product antagonises the effects of prostaglandin F_2-alpha and oxytocin and is antagonised by β-adrenergic blocking agents. In case of accidental overdose, a beta-blocker such as propranolol may be used as antidote. If used during pregnancy, treatment must be discontinued at the expected time of delivery since uterine contractions may be abolished under its influence.

8. ADVERSE REACTIONS

Clenbuterol may cause side effects such as sweating (mainly neck region), muscle tremor, tachycardia, slight hypotention or restlessness. These are typical for β-agonists and occur rarely. If you notice any serious side effects or other effects not mentioned, please inform your veterinary surgeon.

9. TARGET SPECIES

Horses

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

Dosage: For oral use. Twice daily administration of 0.8 micrograms of clenbuterol hydrochloride per kg bodyweight. This dose corresponds to twice daily administration

of 5 g of the granules per 100 kg bodyweight. The granules should be added to the feed. Treatment should be continued for as long as necessary. The measuring scoop provided with the 500 g pack contains 10 g when full. A scored line on the scoop indicates a halfmeasure (5 g).

11. ADVICE ON CORRECT ADMINISTRATION

Add to feed immediately before administration. Discard any remaining medicated feed.

12. WITHDRAWAL PERIOD

Horses intended for human consumption should not be slaughtered until 28 days after the end of treatment.

Do not use in animals producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

14. SPECIAL WARNING(S)

User precautions

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 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.

15. EXPIRY DATE

Expiry Date:

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

For animal treatment only.

UK : Vm 08327/4308 :

POM-V

To be supplied only on veterinary prescription.

IE : VPA 10007/010/001 :

POM

Prescription Only Medicine

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

Keep out of reach and sight of children.

20. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 08327/4308

IE: VPA 10007/010/001

21. MANUFACTURER'S BATCH NUMBER

Batch No:

22. OTHER INFORMATION

To be supplied only on veterinary prescription.

Pharmaceutical precautions

Protect from light. Do not store above 30°C.

Add to feed immediately before administration. Discard remaining medicated feed. Discard unused material. Do not use after the stated expiry date.

Package Quantities

Screw top polyethylene bottle containing 500 g granules.

Approved 09 November 2018