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

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

Manufacturer for batch release
Klocke Pharma Service GmbH
D–77763 Appenweier, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sputolosin Oral Powder 5mg/g

Bronchial secretolytic

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

1 g of powder contains 5 mg of dembrexine hydrochloride monohydrate. (Equivalent to 4.372 mg of dembrexine per g.)

4. PHARMACEUTICAL FORM

Oral powder for addition to feed

5. PACKAGE SIZE

420 g

6. INDICATION(S)

For the symptomatic treatment of respiratory diseases in horses where an abnormal amount of mucus of increased viscosity is present.
Dembrexine reduces the viscosity of respiratory mucus by fragmenting the sputum fibre network, and increasing pulmonary surfactant and respiratory compliance.
To be used alone or as an adjuvant therapy.

7. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient.
Care/precautions should be taken when using this product to avoid skin contact, eye contact and/or inhalation of the dust. Medical advice should be sought if you feel unwell after using this product.
Sputolosin has not been tested in pregnant mares, however, reproduction studies using dembrexine in laboratory animals show no teratogenic effect. Where Sputolosin has been administered to pregnant mares, no adverse effects have been reported.
Dosage upto 15 times the therapeutic dose did not cause any adverse reactions.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Horse

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

Twice daily administration of 0.3 mg active ingredient per kg bodyweight. Adult horses (500 kg) - 6 level measures (= 30 g) should be added to the feed twice daily (5 g measure enclosed). For smaller horses, ponies and foals the dose should be given pro rata according to bodyweight, i.e. at a rate of 2 level measures (10 g) per 170 kg. Add to the feed immediately prior to administration. Discard any remaining medicated feed. An improvement in clinical signs is usually seen within 5 days. Treatment should be continued until complete remission occurs (usually a total period of 12-14 days) but should not exceed 28 days. The horse’s condition should be reassessed after this period before any further treatment is proposed. In cases complicated by the presence of microorganisms or where pyrexia is present, the simultaneous use of suitable chemotherapeutic agents is recommended.

11. ADVICE ON CORRECT ADMINISTRATION

To be used in accordance with the directions of a veterinary surgeon.

12. WITHDRAWAL PERIOD

Horses intended for human consumption may not be slaughtered until 1 day after treatment.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place.

14. SPECIAL WARNING(S)

To be supplied only on veterinary prescription.

15. EXPIRY DATE

Expiry Date:

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

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

September 2010

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

For animal treatment only.

UK	POM-V
IE	POM

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

Keep out of reach and sight of children.

20. MARKETING AUTHORISATION NUMBERS

UK: Vm 08327/4303

IE: VPA 10007/018/001

21. MANUFACTURER'S BATCH NUMBER

Batch No:

Approved: 09 November 2018