# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sputolosin Oral Powder 5mg/g

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

**Active substance**

Dembrexine hydrochoride monohydrate 5 mg
(Equivalent to 4.372 mg of dembrexine per g.)

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral powder. Fine, white and free-flowing

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Horses

### 4.2 Indications for use

The product is indicated for the symptomatic treatment of acute, sub-acute and chronic respiratory disease of the upper and lower respiratory tract, where an abnormal amount of mucus of increased viscosity is present..

### 4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.

### 4.4 Special warnings for each target species

None known.

### 4.5 Special precautions for use

**(i) Special precautions for use in animals**
None known.

**(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**
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.

## 4.6 Adverse reactions (frequency and seriousness)

None known.

## 4.7 Use during pregnancy, lactation or lay

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.

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

None known.

## 4.9 Amounts to be administered and administration route

For oral administration in the food at a dose rate of 0.3 mg dembrexine per kg bodyweight twice daily: for example, for a 500kg horse, 30 g (6 level measures) of powder twice daily.

For small horses, ponies and foals the dose is administered pro rata according to the bodyweight, i.e. at a rate of 2 level measures per 170 kg bodyweight.

Add to the feed immediately prior to administration. Discard any remaining medicated feed.

An improvement in clinical signs is usually seen within five days. Treatment should be continued until complete remission occurs (usually a total period of 12 to 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 micro-organisms or where pyrexia is present, the simultaneous use of suitable chemotherapeutic agent is recommended.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known. Dosages up to 15 times the therapeutic dose did not cause any adverse reactions

## 4.11 Withdrawal period(s)

Meat and offal: 1 day

# 5. PHARMACOLOGICAL PROPERTIES

Dembrexine is a benzylamine with mucolytic properties.
ATCvet code : QR05CB90

## 5.1 Pharmacodynamic properties

Dembrexine reduces the viscosity of respiratory mucus by fragmenting the sputum fibre network, and increasing pulmonary surfactant and respiratory compliance.

## 5.2 Pharmacokinetic particulars

Absorption:
Absorption of dembrexine from the gut in the horse is practically complete as evident from the large percentage excreted in the urine. Following oral administration of dembrexine the absolute bioavailability of unchanged drug is about 30% (see also the information under the subheading "Metabolism" below).Steady state concentrations of dembrexine in plasma are reached within 2 days after repeated twice daily oral administration. At that time mean maximum plasma concentrations of 0.15 ng dembrexine/ml are observed about 1 hour post dose.

Distribution:
There is a linear relationship between the dose administered and the plasma concentration observed in the therapeutic dose range. The volume of distribution is approximately 5 l/kg.

Metabolism:
The parent compound trans-dembrexine occurs in plasma, liver and kidneys. Due to a first pass isomerization the stereoisomer of trans-dembrexine, i.e. cis-dembrexine, can also be found. Further metabolites occur as conjugates of dembrexine and there is also some highly polar material. Both trans- and cis-dembrexine are pharmacologically active.

Elimination:
Dembrexine is eliminated with a half life in the order of 8 hours. Approximately 85% of the administered dose is excreted via urine and the remainder via faeces.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Lactose, fine
Lactose, coarse

## 6.2 Incompatibilities

None known.

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Add to feed immediately prior to administration. Discard any remaining medicated feed.

## 6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place.

## 6.5 Nature and composition of immediate packaging

The product is packaged in a polyethylene container with a push-fit polyethylene cap and a measuring spoon (5 g powder). The container is filled with 420 g powder.

### 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 material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

## 8. MARKETING AUTHORISATION NUMBER

Vm 08327/4303

## 9. DATE OF FIRST AUTHORISATION

30 July 1985

## 10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 09 November 2018