1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sputolosin 5 mg/g Oral Powder for Horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Dembrexine hydrochloride monohydrate 5 mg
(Equivalent to 4.372 mg of dembrexine)

Excipients:

Qualitative composition of excipients and other constituents
Lactose, fine
Lactose, coarse

Fine, white and free flowing powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

The veterinary medicinal 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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken to avoid skin contact, eye contact and/or inhalation of the dust when using this veterinary medicinal product.
If you feel unwell after using this veterinary medicinal product seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
This veterinary medicinal product has not been tested in pregnant mares, however, reproduction studies using dembrexine in laboratory animals show no teratogenic effect. Where this veterinary medicinal product has been administered to pregnant mares, no adverse effects have been reported.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
For administration in the food at a dose rate of 0.3 mg dembrexine per kg bodyweight twice daily: for example, for a 500 kg 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 1 day.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QR05CB90

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal 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.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/014/001

8. DATE OF FIRST AUTHORISATION

01/10/1990

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

06/11/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).