SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin 250 mg/g + 50 mg/g oral powder for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:
Sulfadiazine 250 mg
Trimethoprim 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Glucose monohydrate
Silica, colloidal anhydrous

White to off-white powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the treatment of infections in horses caused by micro-organisms susceptible to the combination of trimethoprim and sulfadiazine, such as infections of the upper respiratory tract, the urogenital system and wound infections.

3.3 Contraindications

Do not use in horses with severe liver or kidney disease.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in cases of resistance to trimethoprim and sulphonamides

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Throughout the treatment, animals should have free access to drinking water to avoid possible crystalluria.

In the treatment of new-born animals and animals with liver damage, caution should be exercised.
Renal impairment may cause accumulation, increasing the risk of side effects in long term treatment.
Use the veterinary medicinal product cautiously in horses with blood dyscrasias.
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the veterinary medicinal product and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials due to the potential for cross-resistance.
In case of infections involving purulent conditions, trimethoprim-sulphonamides combinations are not recommended due to a diminished efficacy under such conditions.

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

This veterinary medicinal product contains sulfadiazine, a sulphonamide which can cause hypersensitivity reactions following skin contact, inhalation or accidental ingestion. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to sulphonamides may occasionally be serious.
Contact with the veterinary medicinal product should be avoided. This is especially important for people with known hypersensitivity to sulphonamides.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with filter EN143 when handling this veterinary medicinal product.
Avoid contact with skin. Rubber gloves should be worn when handling this veterinary medicinal product. In the case of contact with skin, wash with soap and water.
If symptoms develop following exposure such as a skin rash or difficulty with breathing and irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands thoroughly after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. urticaria) Inappetence Digestive tract disorder (e.g. loose stool, diarrhoea, colitis) Hepatic disorder Haematological disorder (e.g. anaemia, thrombocytopenia, leucopenia)
Undetermined frequency (cannot be estimated from the available data)	Renal disorder, Urinary tract obstruction[a] Haematuria, Crystalluria

[a] Tubular obstruction

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

The safety of the veterinary medicinal product during pregnancy and lactation has not been assessed in the target species.

Pregnancy and lactation:
Laboratory studies in rats and mice have shown evidence of teratogenic effects at dosages that are above therapeutic dosages.
The use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Potentiated sulphonamides used in conjunction with alpha2-adrenoceptor agonists like detomidine are known to be able to cause fatal arrhythmias in the horse.

3.9 Administration routes and dosage

In-feed use.
The recommended dose is 30 mg of the active substances together (i.e. 25 mg sulfadiazine and 5 mg trimethoprim) per kg body weight, equivalent to 10 g powder per 100 kg, once or twice daily for 5 days. Frequency of dosing is decided on basis of the susceptibility of the pathogens involved and location of the infection.
To ensure a correct dosage body weight should be determined as accurately as possible. The use of suitably calibrated weighing equipment for the administration of the calculated amount of the veterinary medicinal product is recommended when using the jars or parts of the sachets.
The powder can be mixed in a handful of feed immediately prior to dosing. The active ingredients in the powder have a bitter taste. Adding molasses or other sweetener to the feed can facilitate administration of the veterinary medicinal product. The remaining feed should be withheld until half an hour after the horse has eaten the

feed with the medicine. Should a horse continue to reject the medicated feed, treatment should be continued with another pharmaceutical form with the same actives.

The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be affectively controlled.

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

In case of an overdose loose faeces or diarrhoea may be observed. This is generally self-limiting, but if needed can be treated symptomatically, e.g. fluid therapy in case of dehydration**.**

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: 20 days
Milk:
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01EW10

4.2 Pharmacodynamics

Sulfadiazine is a bacteriostatic antibiotic belonging to the sulphonamide group which acts by interference with the synthesis of nucleic acids. Trimethoprim is a reductase inhibitor which also interferes with the synthesis of bacterial nucleic acids. Trimethoprim and sulfadiazine each have a bacteriostatic action, but together they have a synergistic bactericidal effect by intervening in two consecutive steps of the bacterial folate metabolism.
The combination of trimethoprim and sulfadiazine has a broad antibacterial spectrum for both gram positive and gram negative bacteria. 'Chromosomal mutation and plasmid-mediated resistance are described for sulphonamides and its combinations. Resistance is widespread among bacteria isolated from animals reflecting extensive use over time. There is complete cross-resistance between sulphonamides.'

4.3 Pharmacokinetics

At the recommended dosage for horses of 30 mg of the active substances together (i.e. 25 mg sulfadiazine and 5 mg trimethoprim) per kg body weight mean maximum plasma concentrations obtained after a single dose are about 13 micrograms/ml of sulfadiazine and approximately 1.0 micrograms/ml of trimethoprim after 2.3 and 1.7 hours respectively. The plasma half-life is approximately 7 hours for sulfadiazine and about 3 hours for trimethoprim. Both substances are metabolized in the liver;

sulfadiazine by acetylation and glucuronidation and trimethoprim by hydroxylation and glucuronidation. Excretion is primarily by the kidney and only to a lesser extent in the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging (jars): 3 months
Shelf life after first opening the immediate packaging (sachets): 24 hours if stored dry and re-closed with clip (after folding the edge of the opened sachet).
Shelf life after incorporation into meal: use immediately

5.3 Special precautions for storage

Keep the sachets and jars tightly closed after first opening in order to protect from moisture
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

HDPE (white) jar with a LDPE cap (105 g, 210 g or 420 g).
PP (white) jar with a LDPE cap (840 g).
PET/PE/Alu/PE/LLDPE sachet (5 g, 15 g, 30 g, 60 g or 100 g).

Pack sizes:
Cardboard box with one jar of 105 g, 210 g, 420 g or 840 g oral powder.
Cardboard box with 10, 20 or 28 sachets of 5 g, 15 g, 30 g or 60 g oral powder.
Cardboard box with 10 sachets of 100 g oral powder.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 50406/4009

8. DATE OF FIRST AUTHORISATION

23 April 2019

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 16 February 2026