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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder
White to off-white powder

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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 product cautiously in horses with blood dyscrasias.
Use of the 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 product should be in accordance with official, national and regional antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the 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 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 product.
Avoid contact with skin. Rubber gloves should be worn when handling this 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.
Wash hands thoroughly after use.

4.6 Adverse reactions (frequency and seriousness)

The following adverse reactions can occur:
- Hypersensitivity reactions such as urticaria
- Inappetence
- Gastrointestinal disturbances such as loose faeces, diarrhoea and colitis
- Hepatic or renal disorders.
- Hematologic effects, such as anaemia, thrombocytopenia, or leukopenia
- Haematuria, crystalluria, tubular obstruction

4.7 Use during pregnancy and lactation

Laboratory studies in rats and mice have shown evidence of teratogenic effects at dosages that are above therapeutic dosages.
The safety of the veterinary medicinal product during pregnancy and lactation has not been assessed in the target species; use in pregnant or lactating mares should therefore be avoided.

4.8 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.

4.9 Amounts to be administered and administration route

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 to avoid under dosing. The use of suitably calibrated weighing equipment for the administration of the calculated amount of the 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 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.

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

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**.**

4.11 Withdrawal period(s)

Meat and offal: 20 days
Milk:
Not permitted for use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Combinations of sulphonamides and trimethoprim, incl. derivatives, sulfadiazine and trimethoprim.
ATCvet code: QJ01EW10

5.1 Pharmacodynamic properties

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.'

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose monohydrate
Silica, colloidal anhydrous

6.2 Major incompatibilities

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

6.3 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

6.4 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.

6.5 Nature and composition of immediate packaging

White HDPE jars with a LDPE cap containing 105 g, 210 g or 420 g powder.
White PP jars with a LDPE cap containing 840 g powder.
PET/PE/Alu/PE/LLDPE sachets containing 5 g, 15 g, 30 g, 60 g or 100 g powder.
Cardboard boxes containing 10, 20 or 28 aluminum sachets each containing 5 g, 15 g, 30 g or 60 g powder.
Cardboard boxes containing 10 aluminum sachets each containing 100 g powder.

Not all pack sizes may be marketed.

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

7. MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 50406/4009

9. DATE OF FIRST AUTHORISATION

23 April 2019

10. DATE OF REVISION OF THE TEXT

April 2019

Approved: 23 April 2019