SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin vet. (333 mg/g + 67 mg/g) Oral Paste for

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains :

Active substances:
Trimethoprim 66.7 mg
Sulfadiazine 333.3 mg

Excipient(s):
Chlorocresol 2.0 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral paste.
White to almost white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

Treatment of infections in horses caused by bacteria sensitive to the combination of trimethoprim and sulfadiazine, particularly:
Respiratory tract infections associated with *Streptococcus* spp. and *Staphylococcus aureus*;
Gastrointestinal infections associated with *E. coli*;
Urogenital infections associated with beta-hemolytic streptococci;
Wound infections and open or drained abscesses associated with *Streptococcus* spp. and
Staphylococcus aureus.

4.3 Contraindications

Do not use in horses known to be hypersensitive to sulfonamides, with serious hepatic or renal insufficiency nor with blood dyscrasias,
Do not use this product to treat abscesses without proper drainage.
Do not use in case resistance to sulphonamides occurs.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

During treatment with the product animals must have free and easy access to drinking water.
Do not use the same syringe in more than one animal.
Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the combination of Sulfadiazine and Trimethoprim, and may decrease the effectiveness of treatment with sulphonamides and/or trimethoprim due to the potential for cross-resistance.

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

People with known hypersensitivity to sulfonamides should avoid contact with the veterinary medicinal product.
In case of reaction of hypersensitivity after exposure (such as skin rash), seek medical advice and show the package leaflet or the label to the physician. In case of severe reactions (swelling of the face, lips or eyes), seek prompt medical attention and take the package leaflet with you.

4.6 Adverse reactions (frequency and seriousness)

Decrease or loss of appetite can occur in treated animals.
Hematuria, crystalluria, tubular obstruction have been observed.
Loose faeces and diarrhea may develop during treatment with the product. If such effects appear, discontinue treatment immediately and institute appropriate symptomatic measures.

4.7 Use during pregnancy and lactation

Laboratory studies in rats and mice have shown evidence of teratogenic effects. The safety of the product has not been established during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Potentiated sulfonamides used in conjunction with detomidine are known to be able to cause fatal arrhythmias in the horse.

4.9 Amounts to be administered and administration route

Administration route: Oral use.
Posology:
5 mg trimethoprim and 25 mg sulfadiazine per kg body weight per day to a maximum of 5 days.
One syringe is intended for 600 kg bodyweight and each syringe is subdivided into 12 markings.

The equivalent of one marking is sufficient to treat 50 kg of bodyweight and the minimum body weight for treatment is 50 kg.
Directions for use
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing The calculated dose is provided by adjusting the ring on the plunger according to the body weight of the horse.
The paste is administered orally by inserting the nozzle of the syringe through the interdental space and depositing the required amount of paste on the back of the tongue. The animal's mouth should be free of any food. Immediately after administration, elevate the head of the horse for a few seconds to ensure the dose is swallowed.

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

No data available.

4.11 Withdrawal period(s)

Meat and offal: 14 days
Not permitted for use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Sulfonamides and Trimethoprim.
ATCvet code: QJ01EW10

5.1 Pharmacodynamic properties

Both active substances produce a sequential double blockade of bacterial synthesis of folic acid. This results in a synergistic and bactericidal action inhibiting sequential steps in the synthesis of purines, which are required for DNA synthesis. The combination has a broad action against many Gram-positive and Gram-negative bacteria such as staphylococci, streptococci and E.coli.

MIC-breakpoints mg/L for susceptible organisms (EUCAST v. 3.1, February 2013):

Organism	S (susceptible)	R (resistance)
Streptococcus spp.	1	2
Staphylococcus spp.	2	4
Enterobacteriaceae (E. coli)	2	4

(breakpoints are expressed as the trimethoprim concentration, when used in cominbation with sulfamethoxazole)

5.2 Pharmacokinetic particulars

After a single oral administration of 5 mg trimethoprim and 25 mg sulfadiazine per kg body weight to horses, the following parameters (mean ± sd) were observed:

	C_{max} (µg/ml)	T_{max} (hour)	$T_{1/2\ el}$ (hour)

trimethoprim	2.35 ± 0.59	0.91 ± 0.32	2.74 ± 0.91
sulfadiazine	14.79 ± 3.47	1.90 ± 0.76	7.4 ± 1.8

Food intake appeared to affect the pharmacokinetic profile as both trimethoprim and sulfadiazine have been absorbed more rapidly in fasted horses.
Excretion of both actives is chiefly by the kidneys, by both glomerular filtration, and tubular secretion.
Urine concentrations of both trimethoprim and sulfadiazine are several fold higher than blood
concentrations. Neither trimethoprim nor sulfadiazine interferes with the excretion pattern of the other.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Anise oil
Glycerol (E422)
Xanthan gum (E415)
Polysorbate 20 (E432)
Water for injections.

6.2 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: 8 weeks.

6.4. Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

1 or 5 pre-filled multi-dose (Low Density) polyethylene syringes with adjustable screw ring closed with a (Low Density) polyethylene cap, packed in a cardboard box.
Each syringe contains 45 g paste.
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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 19994/4004

9. DATE OF FIRST AUTHORISATION

07 July 2008

10 DATE OF REVISION OF THE TEXT

October 2015

07 October 2015