1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equibactin vet. 333 mg/g + 67 mg/g oral paste for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:
Trimethoprim 66.7 mg
Sulfadiazine 333.3 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	2.0 mg
Anise oil	
Glycerol (E422)	
Xanthan gum (E415)	
Polysorbate 20 (E432)	
Water for injections	

White to almost white paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each 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*.

3.3 Contraindications

Do not use in cases of hypersensitivity to sulfonamides.
Do not use in animals with serious hepatic or renal insufficiency or with blood dyscrasias.
Do not use in case resistance to sulphonamides occurs.
Do not use to treat abscesses without proper drainage.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
During treatment with the veterinary medicinal 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 veterinary medicinal 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 hypersensitivity-type reactions 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.

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):	Decreased appetite, appetite loss Loose stool, diarrhoea
Undetermined frequency (cannot be estimated from the available data):	Haematuria, crystalluria Renal tubular disorder[1]

[1]Tubular obstruction.

If such effects appear, discontinue treatment immediately and institute appropriate symptomatic measures.

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 has not been established during pregnancy.

Pregnancy:
Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and mice have shown evidence of teratogenic effects.

3.8 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.

3.9 Administration routes and dosage

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 body weight and each syringe is subdivided into 12 markings.
The equivalent of one marking is sufficient to treat 50 kg of body weight 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.
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.

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

No data available.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01EW10

4.2 Pharmacodynamics

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 combination with sulfamethoxazole)

4.3 Pharmacokinetics

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.

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: 8 weeks.

5.3 Special precautions for storage

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

1 or 5 pre-filled multi-dose (Low Density) polyethylene oral 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.

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

Le Vet BV

7. MARKETING AUTHORISATION NUMBER(S)

VPA10816/004/001

8. DATE OF FIRST AUTHORISATION

21/07/2008

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

11/09/2025

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).