PARTICULARS TO APPEAR ON THE OUTER PACKAGE

(OUTER CARTON / CARDBOARD BOX)

Read the package leaflet before use.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:

Active substances:
Trimethoprim 66.7 mg
Sulfadiazine 333.3 mg

Excipients per gram:
Chlorocresol 2.0 mg

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

Multi-dose syringe with 45 gram paste.
5 multi-dose syringes with 45 gram paste.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

EXP month/year .....
Shelf-life after first opening the immediate packaging: 8 weeks.
Once opened, use by …….

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Keep the syringe in the outer carton

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder
Name: Le Vet B.V.
Address: Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

……

17. MANUFACTURER'S BATCH NUMBER

Batch number .....

MINIMUM PARTICULARS TO APPEAR ON LARGE IMMEDIATE PACKAGING UNITS

(Pre-filled multidosis PE SYRINGE with adjustable screw ring closed with a PE cap)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 gram contains

Trimethoprim	66.7 mg
Sulfadiazine	333.3 mg
Chlorocresol	2.0 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Syringe containing 45 gram paste.

4. ROUTE(S) OF ADMINISTRATION

For oral administration.

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Batch number .....

7. EXPIRY DATE

EXP (month/year) .....
Once opened, use by 8 weeks.
Do not refrigerate or freeze.
Keep out of the sight and reach of children.
Keep the syringe in the outer carton.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
To be supplied on veterinary prescription.

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Name: Le Vet B.V.
Address: Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Name: Produlab Pharma B.V.
Address: Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:

Active substances:
Trimethoprim 66.7 mg
Sulfadiazine 333.3 mg

Excipients
Chlorocresol 2.0 mg

Description
A white to almost white suspension.

4. INDICATION(S)

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*.
Do not use in case resistance to sulphonamides occurs.

5. CONTRAINDICATIONS

Do not use in animals known to be hypersensitive to sulfonamides, in animals with serious hepatic or renal insufficiency or in horses with blood dyscrasias,
In case of treatment of purulent infections do not use this product without appropriate drainage.
Do not use in case resistance to sulphonamides occurs

6. ADVERSE REACTIONS

Decrease or loss of appetite can occur in treated animals.
Hematuria, crystalluria, tubular obstruction have been observed.
Loose faeces and diarrhoea may develop during treatment with the product. If such effects appear, discontinue treatment immediately and institute appropriate symptomatic measures.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only.
5 mg trimethoprim and 25 mg sulfadiazine per kg body weight per day to a maximum of 5 days.
The dose may be administered once daily, or the daily dose may be divided and administered at 12 hourly intervals.
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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Keep out of the sight and reach of children.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the immediate packaging: 8 weeks.

12. SPECIAL WARNING(S)

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
Persons with known hypersensitivity to sulfonamides must not handle the product.
In case of reaction of hypersensitivity after exposure (such as skin rash), seek a medical advice and show the doctor this warning. Severe reactions (swelling of the face, lips or eyes), urgent medical attention should be required.

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.

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.

Overdose (symptoms, emergency procedures, antidotes), if necessary
No data available

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

08-11-2015

15. OTHER INFORMATION

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the outer carton."

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)

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 severalfold higher than blood concentrations. Neither trimethoprim nor sulfadiazine interferes with the excretion pattern of the other.

Package (size)
1 or 5 pre-filled multi-dose (LD) polyethylene syringes with adjustable screw ring closed with a (LD) polyethylene cap, packed in a cardboard box.
Each syringe contains 45 g paste.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.