

**IRISH MEDICINES BOARD ACT 1995**

**EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007**

**(S.I. No. 786 of 2007)**

VPA:**10816/004/001**

Case No: 7001670

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

**Le Vet B.V.**

**Willeskop 212, 3421 G W Ouderwater, Netherlands**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

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

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in Part 2 of the said Schedule.

This authorisation, unless previously revoked, shall continue in force from **21/07/2008** to **20/07/2013**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active substances:

Per gram:

Trimethoprim	66.7 mg
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Sulfadiazine	333.3 mg
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##### Excipient(s):

Chlorocresol	2.0 mg
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For a 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.

##### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

### **Special precautions for use in animals:**

To avoid under- or overdosing assess bodyweight and dosage as accurately as possible before dosing.

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.

### **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.

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, lactation or lay

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 sub-divided into 12 markings.

The equivalent of one marking is sufficient to treat 50 kg of bodyweight and the minimum bodyweight for treatment is 50 kg.

Directions for use

Horse weight should be accurately determined for the correct use of the paste.

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

Not known.

## 4.11 Withdrawal Period(s)

Meat and offal: 14 days

Not permitted for use in mares producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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.

5.2 Pharmacokinetic properties

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 <sub>max</sub> (microgram/ml)	T <sub>max</sub> (hour)	T <sub>1/2 el</sub> (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

Do not mix this product with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 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**

Pre-filled multi-dose (LD) polyethylene syringe with adjustable screw ring closed with a (LD) polyethylene cap, packed in a cardboard box.

Each syringe contains 45 g paste.

## **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

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.  
Willeskop 212  
3421 GW Oudewater  
The Netherlands

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10816/4/1

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

21<sup>st</sup> July 2008

## **10 DATE OF REVISION OF THE TEXT**