

**IRISH MEDICINES BOARD ACT 1995**

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

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

VPA: **10989/031/001**

Case No: 7004644

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:

**Eurovet Animal Health B.V.**

**Handelsweg 25, 5531 AE Bladel, 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:

**Vetrisul Powder**

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 the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2008**.

Signed on behalf of the Irish Medicines Board

---

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetrisul Powder

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances

Trimethoprim 40 mg

Sulfadiazine (as sulfadiazine sodium) 200 mg

For a full list of excipients see section 6.1.

#### 3 PHARMACEUTICAL FORM

Powder for oral administration.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Calves and horses.

##### 4.2 Indications for use, specifying the target species

For the treatment of infections caused by micro-organisms susceptible to the combination of trimethoprim and sulfadiazine.

##### 4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances.

Do not use in animals with impaired renal or kidney function.

Do not use where there are diseases with decreased urine production (oliguria, anuria) and aciduria.

Do not administer to calves with functional rumens.

Do not administer to foals under 4 days of age.

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

None.

## **4.5 Special precautions for use**

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

Prolonged treatment increases the risk of blood dyscrasias or folic acid deficiency.  
After extended treatment of high dosages, crystalluria may occur.

### **Special Precautions to be taken by the Person Administering the Medicinal Product to Animals**

Avoid skin contact with the powder; avoid inhaling dust particles.

## **4.6 Adverse reactions (frequency and seriousness)**

Hypersensitivity reactions may occur (rare).

## **4.7 Use during pregnancy, lactation or lay**

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

## **4.8 Interaction with other medicinal products and other forms of interaction**

Sulfonamides are incompatible with para-aminobenzoic acid and its esters (procaine, tetracaine).

## **4.9 Amounts to be administered and administration route**

For oral administration.

In calves, Vetrisul powder should be administered via the milk (-replacer) or the drinking water. In horses, it is recommended to mix the powder with a small amount of feed (mash).

The general dosage is 4 mg trimethoprim and 20 mg sulfadiazine per kg bodyweight, repeated once daily for 3-5 days, according to clinical response.

Calves: 5g of Vetrisul powder per 50 kg bodyweight, once daily, for 3-5days.

Horses: 10g of Vetrisul powder per 100 kg bodyweight, once daily, for 3-5 days.

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

See point 4.6.

## **4.11 Withdrawal Period(s)**

Calves: Meat and offal: 30 days.

Horses: Meat and offal: 60 days.

Not permitted for use in lactating animals producing milk for human consumption.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; Sulfonamides and Trimethoprim; Sulfadiazine and Trimethoprim.

ATCvet Code: QJ01EW10.

### 5.1 Pharmacodynamic properties

Trimethoprim (TMP) is a diaminopyrimidine, a synthetic folic acid antagonist. Sulfadiazine (SDZ) is a broad-spectrum antimicrobial agent belonging to the sulphonamide group.

Trimethoprim is generally bacteriostatic and has a broad spectrum of activity against gram-positive and gram-negative bacteria. Sulfadiazine inhibits bacteria, chlamydiae, toxoplasma and other protozoal agents such as coccidia. Trimethoprim and sulfadiazine inhibit sequential steps in the synthesis of tetrahydrofolic acid, an essential metabolic cofactor in bacterial synthesis of purine and subsequently, DNA. A synergistic and bactericidal effect occurs when trimethoprim is combined with sulfadiazine.

### 5.2 Pharmacokinetic properties

Following oral administration, the absorption of both drugs is relatively fast and complete. SDZ is relatively hydrophilic and therefore concentrations in most tissues are generally lower than in plasma, with exception of the kidney (and liver). As TMP is more lipophilic, it penetrates most tissues better than SDZ, which is reflected by a higher distribution volume. TMP and SDZ are extensively metabolised, but differences between the species occur. SDZ is eliminated with the urine, faeces and bile (and with the milk). However, the kidney is the organ primarily involved in the excretion of the drug. TMP is also excreted primarily in the urine, but it is partially also eliminated through the faeces (and the milk). Aciduria stimulates elimination of TMP, but may cause crystalluria by SDZ.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose

### 6.2 Incompatibilities

Do not mix with any other medicinal product.

### 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after dilution or reconstitution according to directions: 24 hours

### 6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

### 6.5 Nature and composition of immediate packaging

Sealed 4 layer sachet (clay-coated paper/polyethylene/aluminium foil/ionomer) containing 25g white to creamy white powder.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Eurovet Animal Health B.V.  
Handelsweg 25  
5531 AE Bladel  
The Netherlands

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

VPA 10989/031/001

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

30th September 2008

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