

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10989/009/001**

Case No: 7004641

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 Solution for Injection

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 Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Trimethoprim 40 mg

Sulphamethoxazole 200 mg

Excipient

Benzyl Alcohol 9.0 mg

N, N-Dimethylacetamide 170 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Infections caused by micro-organisms susceptible to trimethoprim and/or sulfamethoxazole.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals with impaired liver or kidney function.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

Avoid skin contact with the solution.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, temporary swellings at the injection site may occur (for this reason subcutaneous injections should be avoided).

Folic acid deficiency, crystalluria and/or blood dyscrasias may occur, especially if treatment is prolonged.

4.7 Use during pregnancy, lactation or lay

The active ingredients are excreted in milk and may thus be transmitted to sucklings. No adverse effects are anticipated at the recommended dose during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

The combination is in theory incompatible with para-aminobenzoic acid and esters of it (lidocaine, procaine etc.).

4.9 Amounts to be administered and administration route

Vetrisul 100 ml injection is indicated for intramuscular administration only.

The general dose is: 1 ml per 10-15 kg body weight daily (equivalent to 2.6 - 4 mg trimethoprim/kg and 13-20 mg sulfamethoxazole/kg). This dose may be repeated daily for a period of 3 - 5 days, according to clinical response.

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

Folic acid deficiency, crystaluria and/or blood dyscrasias may occur, especially if treatment is prolonged.

4.11 Withdrawal Period(s)

Meat and offal: 35 days.

Milk: 5 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

ATCvet Code: QJ01EW11.

5.1 Pharmacodynamic properties

Trimethoprim (TMP) is a diaminopyrimidine, a synthetic folic acid antagonist. Sulfamethoxazole (SMX) is a broad-spectrum antimicrobial agent belonging to the sulphonamide group of antibiotics.

Trimethoprim is generally bacteriostatic and has a broad spectrum of activity against gram-positive and gram-negative bacteria. Sulphamethoxazole inhibits bacteria, chlamydiae, toxoplasma and other protozoal agents such as coccidia. Trimethoprim and sulphamethoxazole 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 sulfamethoxazole.

5.2 Pharmacokinetic properties

Following intramuscular administration the absorption of both drugs is rapid. Maximum TMP serum levels are measured 1-2 hours after intramuscular injection; maximum SMX serum levels are measured 1½-4 hours after injection.

SMX 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 SMX, which is reflected by a higher distribution volume. TMP and SMX are extensively metabolised, but differences between the species occur.

SMX 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 SMX.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
N,N-Dimethylacetamide
Glycerol formal
Water for Injection

6.2 Incompatibilities

Do not mix with any other 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: 14 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Amber Type II 100 ml glass vial, sealed with a butyl rubber stopper, with an aluminium cap.

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 10989/009/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT