Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Septotryl II Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances		
Trimethoprim	40	mg
Sulfadiazine	200	mg
Excipients		
Chlorocresol	1	mg
Sodium Formaldehyde Sulfoxylate	1	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, Cattle, Pigs, Dogs, Cats

4.2 Indications for use, specifying the target species

Septotryl II Injection is indicated for the treatment of systemic infections caused by or associated with organisms sensitive to Trimethoprim:Sulphadiazine combination. The spectrum of activity includes both Gram positive and Gram negative organisms including:

Actinobacilli
Bordetella spp.
Corynebacteria
Escherichia coli
Haemophilus spp.
Klebsiella spp.
Pasteurella spp.
Salmonella spp.
Staphylococci
Streptococci

4.3 Contraindications

Septotryl II Injection should not be given by routes other than those recommended.
Do not use in cases of hypersensitivity to the active ingredients. Do not use in animals with severe liver parenchymal damage or blood dyscrasias.
Do not use in horses exhibiting drug induced cardiac arrhythmias, such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Intravenous injections should be administered slowly over as long a period as is reasonably practical in order to avoid possible anaphylactic shock.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic shock, potentially fatal, has been observed on rare occasions following the administration of Potentiated Sulphonamide preparations, particularly after the intravenous route. Veterinary surgeons should be mindful of this possibility during the injection process. For intravenous administration the product should be warmed to body temperature and administered over as long a period as is reasonably practical. At the first sign of intolerance the injection should be interrupted. Intravenous administration should be used with extreme caution and only if therapeutically justified.

Local reaction characterised by swelling and/or hardness may be observed at the injection site following treatment. These lesions are of a transient nature, resolving within one week after treatment.

4.7 Use during pregnancy, lactation or lay

Septotryl II Injection can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer to horses exhibiting drug-induced cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.

4.9 Amounts to be administered and administration route

To ensure a correct dosage body weight should be determined as accurately as possible.

Cattle and Pigs:

The recommended dose rate is 15 mg of active ingredients per kilogram bodyweight (1 ml per 16 kg bodyweight) by intramuscular or slow intravenous injection.

Horses:

The recommended dose rate is 15 mg of active ingredients per kilogram bodyweight (1 ml per 16 kg bodyweight), by slow intravenous injection.

Dogs and Cats:
The recommended dose rate is 30 mg of active ingredients per kilogram bodyweight (1 ml per 8 kg bodyweight), by subcutaneous injection only.

Treatment may be repeated until 2 days after the symptoms have resolved, up to a maximum of five days.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal:
Cattle: 12 days
Pigs: 20 days
Horses: 28 days

Milk: 48 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Antibacterials for systemic use, sulfadiazine and trimethoprim.
ATCvet code: QJ01EW10

5.1 Pharmacodynamic properties

Sulfadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and Trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which converts dihydrofolic acid into tetrahydrofolic acid. TMP and SDZ act together synergistically with a double-blockage mode of action. The combination is bactericidal, inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis. TMP/SDZ combinations have a broad bactericidal action against many gram-positive and gram-negative aerobic bacteria, a large proportion of anaerobic bacteria, chlamydia and protozoa.

5.2 Pharmacokinetic properties

Sulphadiazine is moderately well absorbed after oral administration (rapidly by pigs but more slowly by cattle), is protein bound only to a limited extent and is well distributed. Metabolism occurs in the liver and the major products are acetylated derivatives which are excreted mainly by glomerular filtration. The plasma half-lives in cattle, pigs and dogs are 2, 3 and 4 hours respectively. The half-life when given to horses in combination with Trimethoprim is 3 hours. Trimethoprim is a weak base with low water solubility. It is readily absorbed from the gastro-intestinal tract, although it is degraded in the rumen. Trimethoprim is about 65% protein bound but, being lipid soluble, readily penetrates cellular barriers to become widely distributed. It is partly oxidised and conjugated in the liver and the metabolites, plus unchanged Trimethoprim, are excreted in the urine.

The degree of metabolism varies: 80% in the dog and almost 100% in the cow. The half-life is also variable: 4 hours in the horse, 2 hours in the pig and 1 hour in the cow. Given the wide interspecies variability in the half-life of both actives, it is not possible to attain pharmacokinetic matching of the two compounds, but there is evidence that synergism occurs over a wide range of dose ratios. The combination of 1:5 Trimethoprim:Sulphadiazine is well documented for veterinary use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium Formaldehyde Sulfoxylate
Disodium Edetate
N-Methyl Pyrrolidone
Sodium Hydroxide
Water for Injections

6.2 Incompatibilities

None known.

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: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Do not freeze.
Crystallisation of the product at low temperature can be reversed by gentle warming.

6.5 Nature and composition of immediate packaging

100 ml Amber Type II (Ph. Eur.) glass vial, sealed with a nitrile rubber stopper.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
First Floor, Segrave House
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/026/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd March 1994
Date of last renewal: 23rd March 2009

10 DATE OF REVISION OF THE TEXT

August 2015