Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Roscosulf 400 mg/ml Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substance	
Sulfadimethoxine	400 mg
Excipients	
Benzyl Alcohol	10 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, pigs and sheep.

4.2 Indications for use, specifying the target species

Infections due to microorganisms susceptible to sulfadimethoxine including especially respiratory tract and urinary tract infections.

4.3 Contraindications

Do not use in pregnant animals.
Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

In cattle, slow intravenous administration is recommended.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Transient discomfort and a very mild local tissue irritation may be occasionally observed following intramuscular administration.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

ROSCOSULF is suitable for intravenous administration to cattle, and for intramuscular administration to cattle, pigs and sheep. Where dose volumes at IM administration exceed 15 ml, the dose should be divided and administered at separate sites.
Treatment should commence with an initial dosage followed up by maintenance therapy to be continued until the animal has been free from symptoms or the temperature has been normal for 24 hours.
The duration of treatment depends on clinical response. In most cases 2-3 days are adequate.

Dosage - cattle, pigs and sheep:
Initial dose: 1 ml per 10 kg b.w. (40 mg/kg), once
Maintenance dose: 1 ml per 20 kg b.w. (20 mg/kg) once a day, repeat after 24 or 48 hours.

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

None.

4.11 Withdrawal Period(s)

Withholding time after the last treatment (IV or IM):
Meat: 28 days
Milk: 7 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ROSCOSULF is a 40 % aqueous solution for IV and IM injections to cattle, pigs and sheep. Its formulation ensures rapid absorption from the injection site. Because of a long elimination half-life, it provides the therapeutic serum level for at least 24 hours. High concentration of sulfadimethoxine in ROSCOSULF™ ensures that smaller volumes need to be injected. Sulfadimethoxine inhibits synthesis of bacterial folic acid. This results in suppression of protein synthesis, inhibition of growth, and multiplication of microorganisms which cannot utilize preformed folate. Sulfadimethoxine's effect is bacteriostatic. Sulfadimethoxine is active against aerobic Gram-positive cocci and some rods and many Gram-negative rods. This includes: Actinobacillus pleuropneumonia, Bordetella bronchiseptica, Pasteurella, Salmonella, Streptococcus, E.coli, and Klebsiella.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate
Sodium Hydroxide
Benzyl Alcohol
Propylene Glycol
Disodium Edetate
Water for Injections

6.2 Incompatibilities

Should not be mixed with other drugs.

6.3 Shelf-life

Two years if the vial has not been opened.
Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Amber 100 ml glass vial, Type I with bromobutyl stoppers and aluminium caps containing a clear yellow sterile solution for injection.

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

Ceva Animal Health Limited
Unit 3, Anglo Office Park
White Lion Road
Amersham, Bucks
HP7 9FB
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/024/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003

10 DATE OF REVISION OF THE TEXT

10th November 2011