Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 24% 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
N-Methyl Pyrrolidone	0.5 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A clear, yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cattle, pigs, cats and dogs.

4.2 Indications for use, specifying the target species

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

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

4.3 Contraindications

The product should not be administered intraperitoneally.
Do not administer to animals known to be hypersensitive to the active ingredients.
Do not administer to animals with known sulphonamide sensitivity or severe liver or kidney parenchymal damage or blood dyscrasias.

4.4 Special warnings for each target species

Adequate drinking water should be available during the therapeutic effect of the product.
Avoid the introduction of contamination during use.
Should any apparent growth or discolouration occur the product should be discarded.

4.5 Special precautions for use

Special precautions for use in animals

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.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the product and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials, due to the potential for cross-resistance.

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

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic shock, potentially fatal, has been observed on rare occasions following 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 and Lactation lactation

The safety of the veterinary medicinal product has not been established in horses, cattle, pigs, cats and dogs during pregnancy and lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

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, bodyweight 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).
Administration is by intramuscular or slow intravenous injection.
Maximum recommended volume to be administered at a single intramuscular site: 15 ml of product.
Horses:
The recommended dose rate is 15 mg of active ingredients per kilogram bodyweight (1 ml per 16 kg bodyweight).
Administration is by slow intravenous injection only.
Dogs and Cats;
The recommened dose rate is 30 mg of active ingredients per kilogram bodyweight (1ml per 8 kg bodyweight).
Administration is by subcutaneous injection only.
For all species a single injection may be sufficient in uncomplicated conditions, but in severe infections treatment may be repeated until two days after the symptoms have been resolved up to a maximum of five days.

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

Not applicable

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animal:
Cattle: 12 days from last treatment
Pigs: 20 days from last treatment
Horses:28 days from last treatment

Milk: 48 hours from last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combinations of sulphonamide and trimethoprim, sulfadiazine and trimethoprim. ATCvet code: QJ01EW10.

5.1 Pharmacodynamic properties

Sulphadiazine (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-blockade 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulfoxylate Disodium Edetate
Chlorocresol
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

Store below 25ºC.

Do not freeze.

Protect from light.

Crystallisation of the product, which can occur at low temperatures, can be reversed by gentle warming.

6.5 Nature and composition of immediate packaging

The product is presented in 50 ml and 100 ml amber Type II glass vials sealed with nitryl rubber bungs. Not all pack sizes may be marketed.

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

Norbrook Laboratories (Ireland) Limited

Rossmore Industrial Estate

Monaghan

Ireland

8 MARKETING AUTHORISATION NUMBER(S)

22664/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01October 1988

Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT