1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 240 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Trimethoprim	40 mg
Sulfadiazine	200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	1 mg
Sodium Formaldehyde Sulfoxide	1 mg
N-Methyl Pyrrolidone	0.5 ml
Disodium Edetate	
Sodium Hydroxide	
Water for Injection	

A clear, yellow aqueous solution.

3 CLINICAL INFORMAITON

3.1 Target Species

Horses, cattle, pigs, cats and dogs.

3.2 Indications for use for each target species

The veterinary medicinal 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
Bordetella spp.
Corynebacteria
Eschericia coli
Haemophilus spp.
Klebsiella spp.
Pasteurella spp.
Salmonella spp.
Staphylococci
Streptococci

3.3 Contraindications

The veterinary medicinal product should not be administered intraperitoneally.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients. Do not use in animals with known sulphonamide sensitivity or severe liver or kidney parenchymal damage or blood dyscrasias.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for use in the target species:

Use of the veterinary medicinal 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 veterinary medicinal 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.
Veterinary surgeons should be mindful that anaphylactic shock, potentially fatal, may occur following administration of Potentiated Sulphonamide preparations. For intravenous administration, the product should be warmed to body temperature and administrated over as long a period as is reasonably practical. Intravenous administration should be used with extreme caution and only if therapeutically justified.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Cattle, horses, pigs, dogs, cats

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic shock[1]
Very rare (1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[2]

[1] Potentially fatal particularly after intravenous administration (see section 3.5). At the first sign of intolerance, the injection should be interrupted.

[2] Characterised by swelling and/or hardness resolving within one week after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy, 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.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

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 recommended 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal:

Cattle: 12 days.

Pigs: 20 days.

Horses:28 days.

Milk:

48 hours.

4 PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01EW10.

4.2 Pharmacodynamics

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.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Store below 25ºC.
Do not freeze.
Protect from light.
Crystallisation can occur at extremes of temperature. Crystals can be redissolved by gentle warming and / or agitation.

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6 NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7 MARKETING AUTHORISATION NUMBER(S)

VPA22664/021/001

8 DATE OF THE FIRST AUTHORISATION

01/10/1988

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

18/12/2025

10 CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information of this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).