SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 24 Solution For Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Trimethoprim	4.00% w/v
Sulfadiazine	20.00% w/v

Excipients:

Chlorocresol	0.1% w/w
Sodium Formaldehyde Sulphoxylate Dihydrate	0.1% w/w
N-methyl pyrrolidone	51.50 % w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution For Injection
A sterile clear yellow aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Horses
Cattle
Pigs
Dogs
Cats

4.2 Indications for use, specifying the target species

Norodine 24 Injectable Solution is indicated in the treatment of systemic infections caused by or associated with organisms sensitive to the Trimethoprim:Sulfadiazine combination. The spectrum of activity includes both Gram-positive and Gram-negative organisms including:

Actinobacilli
Actinomycae
Bordetella spp
Brucella
Corynebacteria
Escherichia coli
Haemophilus spp
Klebsiella spp
Pasteurella spp

Pneumococci
Proteus
Salmonella spp
Staphylococci
Streptococci
Vibrio

4.3 Contraindications

Norodine 24 Injectable Solution should not be given by routes other than those recommended. Not to be administered intraperitoneally, intra-arterially or intrathecally.

Do not administer to animals with known sulphonamide sensitivity, severe liver parenchymal damage or blood dyscrasias.

4.4 Special Warnings for each target species

None known

4.5 Special precautions for use

Special precautions for use in animals

For intravenous administration the product should be warmed to body temperature and injected slowly over as long a period as is reasonably practical. At the first sign of intolerance the injection should be interrupted and shock treatment initiated.
Adequate drinking water should be available during the therapeutic effect of the product.

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

Care should be taken to avoid accidental injection and contact with the skin. Wash hands after use.
Sulphonamides may cause hypertensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypesensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.
3. 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 by the intravenous route. Veterinary surgeons should be mindful of this possibility during the injection process.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in < Horses, Cattle, Pigs, Dogs, Cats during pregnancy, lactation, lay 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

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.

Norodine 24 Injectable Solution may be administered by intravenous injection when rapid blood levels of trimethoprim and Sulfadiazine are required.

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.

The recommended site in dogs is the loose skin at the top of the neck.

A single injection may be sufficient in uncomplicated conditions, but in severe infections it may be repeated daily until 2 days after symptoms resolve, up to a maximum of 5 days.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

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

No treatment specified.

4.11 Withdrawal period

Not to be used for horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

Cattle: Meat – 12 days
Milk – 48 hours

Pigs: Meat – 20 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

ATC Vet 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-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, and a large proportion of anaerobic bacteria.

Sulfadiazine is moderately well absorbed after oral administration (rapidly by sheep and 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:Sulfadiazine is well documented for veterinary use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium Formaldehyde Sulphoxylate Dihydrate
Disodium Edetate Dihydrate
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 of the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.
Protect from freezing.
Following withdrawal of the first dose use the product within 28 days. Discard unused material.
Crystallisation can occur at extremes of temperature. Crystals can be redissolved by gentle warming and / or agitation.

6.5 Nature and composition of immediate packaging

Norodine 24 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 product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4061

9. DATE OF FIRST AUTHORISATION

1 June 1988

10. DATE OF REVISION OF THE TEXT

January 2026

Approved 21 January 2026
Gavin Hall