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Norodine 24 Solution for Injection

Species:Cats, Cattle, Dogs, Horses and other equidae, Pigs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Injections

Active ingredient:Sulfadiazine (Sulphadiazine), Trimethoprim

Product:Norodine 24 Solution for Injection

Product index:Norodine 24

Cattle - milk:48 hours

Cattle - meat:12 days

Pig - meat:20 days

Withdrawal notes:Horse: not to be used in horses intended for human consumption

Incorporating:

Qualitative and quantitative composition

Active substance(s):

Trimethoprim

Sulfadiazine

Excipients:

Chlorocresol

Sodium Formaldehyde Sulphoxylate Dihydrate

N-methyl pyrrolidone

For a full list of excipients, see section Pharmaceutical Particulars

Pharmaceutical form

Solution for Injection.

A sterile clear yellow aqueous solution.

Clinical particulars

Target species

- Horses
- Cattle
- Pigs
- Dogs
- Cats

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

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- *Salmonella* spp
- *Staphylococci*
- *Streptococci*
- *Vibrio*

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.

Special Warnings for each target species

None known

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 hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics.

Allergic reactions to these substances may occasionally be serious.

- Do not handle this product if you know you are sensitive to sulphonamides.
- If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.
- 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 selfinjection.

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

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 Nmethyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

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.

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.

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

No treatment specified.

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

Pharmacological particulars

Pharmacotherapeutic group:

ATC Vet Code: QJ01EW10

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.

Pharmaceutical particulars

List of excipients

Chlorocresol

Sodium Formaldehyde Sulphoxylate Dihydrate

Disodium Edetate Dihydrate

N-Methyl Pyrrolidone

Sodium Hydroxide

Water for Injections

Incompatibilities

None known

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

Special precautions for storage

Do not store above 25°C.

Protect from light.

Protect from freezing.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

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

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.

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.

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Limited

Station Works

NOAH Compendium

Newry

Co. Down

BT35 6JP

Northern Ireland

Marketing Authorisation Number

UK: Vm 02000/4061

Significant changes

Date of the first authorisation or date of renewal

1st June 1988

Date of revision of the text

July 2023

Any other information

Nil.

Legal category

Legal category:POM-V

GTIN

GTIN description:Norodine 24 Injection: 100ml

GTIN:5023534000747