

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICINE:

Norodine 24 Veterinary, Solution for Injection

2. ACTIVE INGREDIENTS:

Each 1 ml contains:

Trimethoprim	40 mg
Sulphadiazine	200 mg

The medicine also contains the excipients:

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

For the full list of excipients, see section 12 "further information".

3. Indications for use:

Indicated in the treatment of sensitive organisms in horses, cattle, pigs, dogs and cats.

Therapeutic Group: Antibiotics

4. Contraindications:

- 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.

5. Adverse reactions:

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. Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link: <https://sideeffects.health.gov.il>

6. Target Species:

Horses, cattle, pigs, dogs and cats

7. Amounts to be administered and administration route:

Cattle and Pigs:

The recommended dose rate is 1 ml per 16 kg bodyweight (15 mg of active ingredients per kilogram bodyweight) by intramuscular or slow intravenous injection.

May be administered by intravenous injection when rapid blood levels of Trimethoprim and Sulphadiazine are required.

Horses:

The recommended dose rate is 1 ml per 16 kg bodyweight (15 mg of active ingredients per kilogram bodyweight), by slow intravenous injection.

Dogs and Cats:

The recommended dose rate is 1 ml per 8 kg bodyweight (30 mg of active ingredients per kilogram 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.

8. Withdrawal period:

Cattle: Meat: 12 days. Milk: 60 Hours

Pigs: Meat: 20 days.

Not for use in horses intended for human consumption.

9. Special warnings and precautions for use:

• Special precautions regarding the use of the medicine for the target animals: None known.

• Special safety precautions regarding the use of the medicine 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.

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.

• 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.

• 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 anesthetic and sedative agents.

• Overdose:

No treatment specified.

• Incompatibilities:

None known.

10. Storage instructions:

• Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and / or infants and thereby prevent poisoning.

• Do not use this medicine after the exp. date on the package. The expiration date refers to the last day of that month.

• Storage conditions: Store below 25°C.

Protect from light.

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

• Do not freeze.

• Shelf-life after first opening the immediate packaging: 28 days. Remains of the product should be destroyed after 28 days.

11. 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 as toxic waste.

Do not dispose in sewage.

12. FURTHER INFORMATION:

• **In addition to the active ingredient the product also contains:**

N-Methyl Pyrrolidone (51.50%w/v), Chlorocresol (0.1%w/v), Sodium Formaldehyde Sulphonylate Dihydrate (0.1%w/v), Disodium Edetate Dihydrate, Sodium Hydroxide, Water for Injection

• **Pharmaceutical form:**

A sterile clear yellow aqueous solution.

• **Packaging sizes:**

Packed in 50 ml and 100 ml glass bottles.

Not all pack sizes may be marketed.

• **Registration holder:** Abic Veterinary Products Ltd., 2 Hanegev Street, Airport City, 7019900

• **Manufacturer:** Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, Northern Ireland, UK

Revised in September 2025 according to MoH's guidelines.

• **Registration number of the medicine in the National Registry of the Ministry of Health:** 082-29-92285-00