PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 24 Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Sulfadiazine	200 mg
Trimethoprim	40 mg

Chlorocresol (preservative) 1 mg and Sodium formaldehyde sulphoxylate dihydrate (antioxidant) 1 mg in an aqueous solution.
N-Methyl Pyrrolidone 0.500 ml.

3. PHARMACEUTICAL FORM

Solution For Injection

4. PACKAGE SIZE

50ml and 100ml

5. TARGET SPECIES

Horses
Cattle
Pigs
Dogs
Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In cattle and pigs administer by intramuscular or slow intravenous injection at a rate of 1 ml/16 kg bodyweight.
In horses administer at a rate of 1 ml/16 kg by slow intravenous injection only.
In dogs and cats administer at a rate of 1 ml/8 kg by subcutaneous injection only.

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

Milk for human consumption must not be taken from a cow during treatment.
Animals must not be slaughtered for human consumption during treatment. Not to be used in horses intended for human consumption, see package leaflet for full warning.

Cattle: Meat - 12 days
Milk - 48 hours
Pigs: Meat - 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Crystallisation of the product at low temperatures can be reversed by gentle warming.
Injections should not be given by routes other than those recommended.
Care should be taken to avoid accidental injection and contact with the skin. Wash hands after use. Sulphonamides may occasionally cause severe allergic reactions.

Further Information: See Package leaflet.

10. EXPIRY DATE

Batch No.:
D.O.M.:
Exp: dd/mm/yy
Once broached use by: __/__/__

11. SPECIAL STORAGE CONDITIONS

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Do not store above 25ºC.
Protect from freezing.
Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:
Norbrook Laboratories Limited
Newry, Co. Down, BT35 6JP
United Kingdom

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4061

17. MANUFACTURER'S BATCH NUMBER

B.N.:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

PACKAGE LEAFLET FOR:

Norodine 24 Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited
Newry, Co. Down
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 24 Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A clear yellow aqueous solution for parenteral administration containing as active ingredients per ml Sulfadiazine 200 mg and Trimethoprim 40 mg.
Preservative: Chlorocresol 1 mg/ml
Antioxidant: Sodium formaldehyde sulphoxylate dihydrate 1 mg/ml
N-Methyl Pyrrolidone 0.500 ml.

4. INDICATION(S)

Norodine 24 is indicated in the treatment of acute, subacute and chronic conditions of bacterial origin in horses, cattle, pigs, dogs and cats. The therapeutic spectrum includes both Gram-negative and Gram-positive bacteria including *Streptococci, Staphylococci, Actinobacilli, Actinomycae, Salmonella, Pasteurella, Pneumococci, Proteus, E. coli, Corynebacteria, Vibrio, Bordetella, Brucella, Klebsiellae* and *Haemophilae.* It is also indicated in species where there may be an existing antibiotic drug resistance. Norodine 24 may be administered in respiratory infections of bacterial origin including rhinitis, pneumonia, bronchitis and in bacterial infections secondary to viral disease such as viral pneumonia or mycoplasma infections. It is also indicated in urogenital tract infections (cystitis, vaginitis, urethritis, nephritis and metritis) and alimentary tract infections (including neonatal diarrhoea and salmonellosis). Other infections include foul-in-the-foot, severe mastitis, bacterial agalactia of sows, and infections of eye, ear and mouth.

5. CONTRAINDICATIONS

Norodine 24 is contraindicated in animals with known sulfonamide sensitivity, severe liver parenchymal damage, or blood dyscrasias.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses
Cattle
Pigs
Dogs
Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For cattle and pigs the dose is 1 ml per 16 kg bodyweight daily by intramuscular or slow intravenous injection.

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

For horses the dose is 1 ml per 16 kg bodyweight by slow intravenous injection.

For dogs and cats the dose is 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 they may be repeated daily until two days after the 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.

9. ADVICE ON CORRECT ADMINISTRATION

Injections should not be given by routes other than those recommended. Not to be administered intraperitoneally.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken from a cow during treatment.
Animals must not be slaughtered for human consumption during treatment.
Not to be used in 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.

Withdrawal Periods:

Cattle:	Meat - 12 days
	Milk - 48 hours
Pigs:	Meat – 20 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Protect from freezing. Crystallization of the product at low temperatures can be reversed by gentle warming. Protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Adequate drinking water should be available during the therapeutic effect of the product.
Do not administer to horses exhibiting drug-induced cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.
Anaphylactic shock, potentially fatal, has been observed on rare occasions following administration of potentiated sulfonamide preparations, particularly by 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 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.
Pregnancy and Lactation
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.

User warnings: 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 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2023

15. OTHER INFORMATION

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

DISTRIBUTED BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

Package Quantities:
Multidose vials of 50 ml and 100 ml.
Not all pack sizes may be marketed.

BN:
D.O.M:
Exp:

ManA 2000
Vm 02000/4061

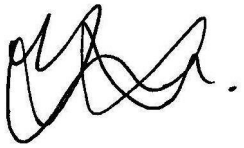
POM-V

To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY

LOGO

UK AUTHORISED VETERINARY MEDICINAL PRODUCT



Approved: 05 July 2023