

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 20 Coated Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Trimethoprim	20 mg
Sulfadiazine	100 mg
Titanium dioxide (E171)	0.27mg

3. PHARMACEUTICAL FORM

Coated tablet.

4. PACKAGE SIZE

100 Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs, Adult Cats: 1 tablet per 4 kg bodyweight, once daily for 5 consecutive days or until 2 days after symptoms have subsided.

When administering the tablet to cats, the tablet should not be broken, chipped or halved.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

6. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use. SULPHONAMIDES may occasionally cause severe allergic reactions.

Further Information: See Package Leaflet.

7. EXPIRY DATE

DOM:

EXP:

8. SPECIAL STORAGE CONDITIONS

Do not store above 25°C
Store in a dry place.
Protect from light.

9. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V

 To be supplied only on veterinary prescription

10. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm: 02000/4096

17. MANUFACTURER’S BATCH NUMBER

B.N.:

PACKAGE LEAFLET FOR:

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
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 20 Coated Tablets

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

Off-white, sugar-coated, unscored, circular antibacterial tablets. Each tablet contains:

Trimethoprim	20 mg
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Sulfadiazine	100 mg
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Titanium dioxide (E171)	0.27mg
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4. INDICATION(S)

Norodine 20 Tablets are indicated for oral use in dogs and adult cats. Together the active ingredients produce a double blockade of folinic acid synthesis in bacteria, resulting in a level of activity much greater than that obtained from either drug alone. *In vitro*, Norodine is effective against most common Gram-positive and Gram-negative bacteria including *Escherichia coli*, *Klebsiella pneumonia*, *Pasteurella* spp, *Streptococcus* spp, *Staphylococcus* spp, *Salmonella* spp, *Corynebacterium* spp, *Proteus mirabilis* and *Citrobacter freundii*.

When susceptible organisms are present Norodine 20 Tablets may be effective in treating the following conditions: alimentary tract infections; respiratory and urogenital infections; skin and wound infections; eye and ear infections.

Use of the 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 epidemiological information.

5. CONTRAINDICATIONS

A low incidence of polyarthropathy and Keratoconjunctivitis Sicca (Dry Eye) has been reported in dogs following oral administration of potentiated sulphonamides. If

either of these conditions occur it is recommended that medication is stopped and that future treatment with similar products is avoided.

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

Dogs
Adult Cats

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

This product should be administered orally by hand.

Dogs and Adult Cats: The daily dose is 30 mg of combined active ingredients per kg bodyweight. This is achieved using the following doses:
One tablet per 4 kg bodyweight daily.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

Maintain adequate fluid intake during treatment. Treatment should be continued for up to five days or until two days after symptoms have subsided.

10. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children
Do not store above 25°C.
Store in a dry place.
Protect from light.
Keep out of the reach of children.

11. SPECIAL WARNING(S)

When given to cats, the tablets should not be divided or crushed before administration.

USER WARNINGS

Take care to avoid skin contact. 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.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2008.

14. OTHER INFORMATION

This product may be used to continue treatment commenced with Norodine 24.

POM-V

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Vm 02000/4096

ManA 2000

Package Quantities:

Plastic containers of 100 tablets.

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1 Saxon Way East
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Northamptonshire
NN18 9EX
United Kingdom

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT
FOR ANIMAL TREATMENT ONLY**

Approved: 10/04/2017

