PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Tub}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 80 Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:	
Trimethoprim	80 mg
Sulfadiazine	400 mg.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

100 or 500 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

When susceptible organisms are present Norodine 80 Tablets may be effective in treating the following conditions: alimentary tract infections, respiratory and urogenital infections, skin and wound infections and eye and ear infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration. Dogs: 1 tablet per 16 kg bodyweight. To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

This dosage form is not suitable for use in cats. Norodine 20 Tablets should be administered to this species. Wash hands after use. Sulphonamides may occasionally cause severe allergic reactions. See package leaflet for full details.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store in a dry place below 25^{o}C. Protect from light.

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

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

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

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4085

17. MANUFACTURER'S BATCH NUMBER

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
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 80 Tablets

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

Each tablet contains:

Trimethoprim	80 mg
Sulfadiazine	400 mg.

4. INDICATION(S)

Norodine 80 Tablets are indicated for oral use in dogs. 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 80 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

This dosage form is not suitable for use in cats. Norodine 20 Tablets should be administered to this species.

6. ADVERSE REACTIONS

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 is avoided. Sulphonamide sensitivity is rare in companion animals but should be considered in cases of unexpected responses to treatment.

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

7. TARGET SPECIES

Dogs

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

The daily dose is one tablet per 16 kg bodyweight administered orally, providing 30 mg of combined active ingredients per kg bodyweight. Treatment should be continued for up to five days or until 2 days after symptoms have subsided.

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

9. ADVICE ON CORRECT ADMINISTRATION

This product should be administered orally by hand.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Store in a dry place below 25oC. Protect from light.

Keep out of the sigh and reach of children.

12. SPECIAL WARNING(S)

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.

For Animal Treatment Only

13. 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 02000/4085

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

Approved: 10/01/2018