PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Tub}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Bolus Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:	
Trimethoprim	200 mg
Sulfadiazine	1.0 g.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

20 or 50 tablets

5. TARGET SPECIES

Calves

6. INDICATION(S)

Norodine Bolus is indicated primarily for the treatment of bacterial scours but may also be used for the treatment of acute salmonellosis and bacterial pneumonia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Calves: 1 tablet per 40 kg bodyweight given orally. Repeated daily until symptoms have resolved, but in cases of salmonellosis and bacterial pneumonia treatment should be continued for five consecutive days. Norodine Boluses may be administered whole, by balling gun, or dispersed in water.

8. WITHDRAWAL PERIOD

Meat: 15 days

9. SPECIAL WARNING(S), IF NECESSARY

Norodine Bolus should not be administered to animals with functionally mature rumens. Protective gloves should be worn whilst handling the product. Wash hands and exposed skin after use. Sulphonamides may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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 *[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 02000/4079

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 Bolus Tablets

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

Each tablet contains:

Trimethoprim	200 mg
Sulfadiazine	1.0 g.

4. INDICATION(S)

Norodine Bolus is indicated primarily for the treatment of bacterial scours but may also be used for the treatment of acute salmonellosis and bacterial pneumonia. Together the active ingredients produce a double blockade of folinic acid synthesis in bacteria, giving 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* spp, *Pasteurella* spp, *Staphylococcus* spp, and *Salmonella* spp,

The boluses are particularly effective against *Escherichia coli* and *Salmonella* spp infections. Official national and regional antimicrobial policies should be taken into account when the product is used.

5. CONTRAINDICATIONS

Norodine Bolus should not be administered to animals with functionally mature rumens.

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

Calves

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

Calves: The daily dose is one tablet per 40 kg (90lb) bodyweight given orally, providing 30 mg of combined active ingredients per kg bodyweight daily.

Treatment should be repeated daily until two days after the symptoms have resolved, but in cases of salmonellosis and bacterial pneumonia treatment should be continued for five consecutive days. Treatment must not be continued for more than five days.

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

9. ADVICE ON CORRECT ADMINISTRATION

Norodine Boluses may be administered whole, by balling gun, or dispersed in water. Dosage by dispersion in water: Disperse each bolus by shaking in about 300 ml of water in dosing bottle. This may be facilitated by crushing the bolus before placing it in the bottle. After dosing by this method any unused material should be discarded.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment. Calves may be slaughtered for consumption only after 15 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25^{o}C. Protect from light. Store in a dry place.

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 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

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 02000/4085

Approved: 10/01/2018