PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE> 500 ML LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intradine 30.89% w/v Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Sulfadimidine 308.9mg, (as Sulfadimidine Sodium 333 mg) with Chlorocresol 1.0 mg as preservative and 1.0 mg Sodium formaldehyde sulphoxylate, as antioxidant.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle, Sheep and Pigs

6. INDICATION(S)

For the treatment of infections caused by or associated with organisms sensitive to Sulfadimidine in cattle, sheep and pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or subcutaneous injection.
Where possible the intravenous route is preferred.
Initial dose - 200 mg/kg bodyweight (1 ml per 1.5 kg bodyweight) Maintenance doses -100 mg/kg bodyweight (1 ml per 3 kg bodyweight) administered at 24 hour intervals.
The maximum period of treatment should be 5 days.

8. WITHDRAWAL PERIOD

Milk/meat should not be taken for human consumption during treatment.
Not for use in sheep producing milk for human consumption.
Sheep & Cattle (meat) - 18 days
Cattle (milk) - 156 hours (6.5 days)
Pigs (meat) - 42 days

9. SPECIAL WARNING(S), IF NECESSARY

USER WARNINGS

Care should be taken to avoid accidental injection. Wash hands after use.
SULPHONAMIDES may occasionally cause severe allergic reactions. See package leaflet for full user warnings.
Normal aseptic precautions should be observed.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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]*

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, Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Ltd.,
1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom.

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4086

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:
UK AUTHORISED VETERINARY MEDICINAL PRODUCT

Discard Date: _____

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

Intradine 30.89% w/v Solution for Injection

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

A clear, pale yellow solution
Each ml contains Sulfadimidine 308.9 mg as sulfadimidine sodium 333.3mg,1.0 mg chlorocresol as antimicrobial preservative and 1.0 mg sodium formaldehyde sulphoxylate, as antioxidant.

4. INDICATION(S)

Intradine is indicated in the treatment of infections caused by or associated with organisms sensitive to Sulfadimidine in cattle, sheep and pigs. Sulfadimidine has been shown to be effective *in vitro* against the following bacterial species:

Bordetella bronchiseptica, Escherichia coli, Mannheimia haemolytica, Salmonella dublin, Salmonella typhimurium and *Actinobacillus lignieresi.*

Specific indications for Intradine include:
enteritis caused by *Escherichia coli, Salmonella dublin* and *Salmonella typhimurium.* salmonellosis and septicaemia caused by *Salmonella dublin* and *Salmonella typhimurium.* pasteurellosis and infections of the respiratory tract caused by *Mannheimia haemolytica.* atrophic rhinitis caused by *Bordetella bronchiseptica* and *Mannheimia haemolytica.* wooden tongue caused by *Actinobacillus lignieresi.*
Intradine has also been shown to be effective in the treatment of coccidiosis and foul in the foot.
Due to likely variability (time, geographical) in the occurrence of resistant bacteria for sulfadimidine, bacteriological sampling and susceptibility testing are recommended.

5. CONTRAINDICATIONS

Intradine is contraindicated in animals with known Sulphonamide sensitivity, severe liver damage and blood dyscrasias.

Therapeutic doses are relatively non-toxic, but agranulocytosis, haemolytic anaemia and avitaminosis-K have been reported following prolonged administration.
Prolonged treatment with Intradine should be avoided, especially in young stock.
Sulphonamides occasionally cause crystalluria, particularly when urinary pH is low. Ensure adequate water intake during treatment, and take particular care in the case of animals suffering from renal damage. To minimize the risk of occasional local

tissue reaction when administering Intradine by subcutaneous injection, the dose should be divided, administered at several sites and well massaged.

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

Cattle, Sheep and Pigs

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

By intravenous or subcutaneous injection. Where possible the intravenous route is to be preferred. Normal aseptic precautions should be observed.

Initial Dose - 200 mg/kg bodyweight (1 ml per 1.5 kg bodyweight)
Maintenance Doses - 100 mg/kg bodyweight (1 ml per 3 kg bodyweight) administered at 24 hour intervals.

The maximum period of treatment should be 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

The volume injected per injection site should not exceed 50 ml in the case of cattle and 10 ml in the case of sheep and pigs when given subcutaneously.
To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD(S)

Milk/meat should not be taken for human consumption during treatment. Not for use in sheep producing milk for human consumption.
Sheep & Cattle (meat): 18 days
Cattle (milk): 156 hours (6.5 days)
Pigs (meat): 42 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Keep out of the reach and sight of children. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

USER WARNINGS
Care should be taken to avoid accidental injection. In case of accidental skin and eye contact, wash affected area thoroughly with water.
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.

Wash hands after use.
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 container in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

20th June 2012

<15. OTHER INFORMATION>

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

Package Quantities:
500 ml bottles for parenteral administration.

ManA 2000
Vm 02000/4086

POM-V To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY
UK AUTHORISED VETERINARY MEDICINAL PRODUCT

Approved: 09/08/2017