SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intradine 30.89% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each ml contains;

Sulfadimidine	308.9mg
(as Sulfadimidine sodium)	333.3mg

Excipients:

Chlorocresol	1.0mg
Sodium formaldehyde sulphoxylate	1.0mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
A clear, pale yellow solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Sheep
Pigs

4.2 Indications for use, specifying the target species

Indicated for the treatment of infections caused by or associated with organisms sensitive to sulfadimidine. Sulfadimidine has been shown to be effective in vitro against the following bacterial species:

Actinobacillus lignieresi
Bordetella bronchiseptica

Escherichia coli
Mannheimia haemolytica
Salmonella dublin
Salmonella typhimurium

The product has been shown to be effective in the treatment of coccidiosis and foul in the foot.

4.3 Contraindications

Contraindicated in known cases of hypersensitivity to sulphonamides and in animals with severe liver damage or blood dyscrasias.

4.4 Special Warnings for each target species

To minimise the risk of injection site tissue reaction following subcutaneous administration it is recommended that the dose be divided, administered at separate sites and well massaged.

4.5 Special precautions for use

Special precautions for use in animals

Due to likely variability (time, geographical) in the occurrence of resistant bacteria for sulfadimidine, bacteriological sampling and susceptibility testing are recommended.

Adequate water must be available during period of treatment. Particular care must be taken in the case of animals suffering from renal damage.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

4.6 Adverse reactions (frequency and seriousness)

Therapeutic doses are relatively non-toxic, but agranulocytosis, haemolytic anaemia and avitaminosis-K have been reported following prolonged administration. Prolonged treatment should be avoided, especially in young stock.

Crystalluria may occur, particularly when urinary pH is low. Ensure adequate water intake during treatment.

Occasional local tissue reactions may occur following subcutaneous injection

4.7 Use during pregnancy, lactation or lay

There is no known contra-indication against use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Administer by intravenous or subcutaneous injection. The intravenous route is preferred.

Normal aseptic precautions should be observed

Recommended initial dose rate is 200 mg per kilogram bodyweight, equivalent to 1 ml per 1.5 kg bodyweight. This should be followed at 24 hour intervals by a maintenance dose of 100 mg per kilogram bodyweight equivalent to 1 ml per 3 kg bodyweight. The maximum period of treatment should be 5 days.

Following subcutaneous administration, it is recommended that the dose is divided, administered at separate sites and well massaged. The volumes 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Agranulocytosis, haemolytic anaemia and avitaminosis-K may result from prolonged administration.

4.11 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 (6.5days)
Pigs (meat): 42 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ01EQ03

5.1 Pharmacodynamic properties

Sulfadimidine is a member of the Sulphonamide group of antibiotics. It exerts its bacteriostatic effect by interfering with the biosynthesis of folic acid in susceptible bacteria. Sulfadimidine competes with paraminobenzoic acid for the enzyme dihydropterate synthetase.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium formaldehyde sulphoxylate
Sodium Hydroxide
Disodium Edetate
Water for Injections

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 Days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

500 ml amber Type II glass vials, sealed with bromobutyl rubber bungs and aluminium caps.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4086

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2nd June 1988

10. DATE OF REVISION OF THE TEXT

13th November 2008