Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Intradine 300 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Sulfadimidine (as Sulfadimidine Sodium)	300.0 mg

Excipients

Chlorocresol	1.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep and Pigs.

4.2 Indications for use, specifying the target species

Intradine 300 mg/ml Solution for Injection is indicated for the treatment of systemic infections caused by or associated with organisms sensitive to sulfonamides including :

Bordetella bronchiseptica
Escherichia coli
Pasteurella haemolytica
Salmonella dublin
Salmonella typhimurium

Specific indications for Intradine 300 mg/ml Solution for Injection in cattle, sheep and pigs include:
- enteritis caused by *Escherichia coli*, *Salmonella dublin* and *Salmonella thypimurium*
- salmonellosis and septicaemia caused by *Salmonella dublin* and *Salmonella thypimurium*
- pasteurellosis and infections of the respiratory tract caused by *Pasteurella haemolytica*
- atrophic rhinitis caused by *Bordetella bronchiseptica* and *Pasteurella haemolytica*.

Intradine 300 mg/ml Solution for Injection has also been shown to be effective in the treatment of coccidiosis.

4.3 Contraindications

Contraindicated in known cases of hypersensitivity to Sulfonamides and in animals with severe liver damage or blood dyscrasias. Do not administer by intramuscular injection.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Adequate water must be available during period of treatment. 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.

Special Precautions to be taken by the Person Administering the Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

Crystalluria may occur when urinary pH is low.

Local reaction characterised by swelling and/or hardness may be observed at the injection sites following treatment. These lesions are of a transient nature, resolving within 1-3 weeks after treatment.

A very rare frequency of anaphylactic-type reactions has been observed following administration of the product. Such reactions may result in fatality.

4.7 Use during pregnancy, lactation or lay

Intradine 300 mg/ml Solution for Injection can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

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

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.

Maximum recommended volume to be administered at a single site:
Cattle – 50 ml
Sheep, pigs – 10 ml

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

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

4.11 Withdrawal Period(s)

Milk for human consumption may only be taken after 144 hours (i.e. at the 13th milking for cows milked twice daily) from the last treatment. Cattle and sheep intended for human consumption should not be slaughtered until 14 days after the last treatment. Pigs intended for human consumption should not be slaughtered until 35 days after the last treatment. Not to be used in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterial for systemic use; Sulfonamides and Trimethoprim; Sulfadimidine.
ATCvet Code: QJ01EQ03.

5.1 Pharmacodynamic properties

Sulfadimidine is a member of the Sulfonamide 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

Sodium Hydroxide
Disodium Edetate
Sodium Formaldehyde Sulfoxylate
Chlorocresol
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 25ºC. Protect from light.

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 products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/027/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT