SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norotyl LA 15% w/v Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Tylosin 15% w/v

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

A suspension for injection.
An oily cream suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

Long-acting product specifically formulated to provide sustained antibacterial activity following a single administration.

Indicated for use in pigs in the treatment of infections caused by, or associated with, organisms sensitive to tylosin which includes organisms in the following genera:

Streptococcus spp,	*Vibrio* spp,
Bacillus spp,	Spirochaetes
Staphylococcus spp,	*Mycoplasma* spp,
Corynebacterium spp,	*Fusiformis* spp,
Clostridium spp,	*Pasteurella* spp,
Erysipelothrix spp,	*Chlamydia* spp

Effective in the treatment and control of a wide range of common systemic, respiratory, urinary and local infections caused by susceptible organisms including:

Pneumonia, erysipelas; swine dysentery; otitis; cellulitis; urogenital tract infections and the control of secondary bacterial invaders sensitive to tylosin in diseases primarily of viral origin.

4.3 Contra-indications

Do not inject intravenously.

4.4 Special Warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Shake the vial before use. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.
The maximum dose to be administered at any one site is 10ml.
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 epidiological information.

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

In case of accidental spillage on to the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists. Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

A transient slight swelling may occur at the injection site which quickly resolves.

4.7 Use during pregnancy, lactation or lay

Safe for use 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

Indicated for intramuscular administration to pigs.

The recommended dose rate is 20 mg tylosin per kg bodyweight, equivalent to 1 ml per 7.5 kg bodyweight.
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

Tylosin has a good margin of safety.

4.11 Withdrawal period

Animals must not be slaughtered for human consumption during treatment.

Meat: 7 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ01FA90

5.1 Pharmacodynamic properties

Tylosin is a member of the macrolide group of antibiotics and its pharmacological properties are similar to other members of that group.
Tylosin inhibits prokaryotic protein synthesis by binding to the 50S ribosomal sub-unit, at, or near, the donor site, thereby sterically preventing peptidyl transfer RNA from binding to the donor site. Elongation of the developing peptide chain as the ribosome moves along the mRNA strand requires translocation of the developing peptide chain from the acceptor site to the donor site. By binding to the donor site, tylosin interferes with this translocation step, thereby inhibiting protein synthesis.
The drug is bacteriostatic but at high concentrations it may be bactericidal. The antibacterial spectrum of tylosin is essentially gram-positive, similar to that of penicillin G, although it is generally more active against fastidious gram-negative species. Tylosin is particularly useful for the treatment of mycoplasmal infections and infections due to gram-positive bacteria.

5.2 Pharmacokinetic properties

Following administration on a single occasion at the recommended dose rate of 20mg/kg there is an early peak plasma level followed by prolonged circulating therapeutic levels of tylosin. As a member of the macrolide group of antibiotics, tylosin characteristically exhibits low plasma levels following parenteral administration with accumulated levels in target tissue which have been reported to be up to 3-4 times the concentrations achieved within serum. Thereby the product allows for an extended period of antibiotic activity in the peripheral circulation and target tissue compared to conventional tylosin injectable formulations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminiun Stearate
Propylene Glycol Dicaprylate/Dicaprate

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.
Following withdrawal of the first dose the product should be used within 28 days.
Discard unused material.
This product does not contain an antimicrobial preservative.
Swab the septum before removing each dose.
Use a dry, sterile needle and syringe.

6.5 Nature and composition of immediate packaging

Supplied in 50 ml and 100 ml Type I siliconised clear glass vials complete with nitryl bungs and aluminium caps.
Not all pack sizes may be marketed.

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
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4136

9. DATE OF FIRST AUTHORISATION

9th February 1998

10. DATE OF REVISION OF THE TEXT

November 2008.