Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylobac 200 mg/ml Solution for Injection for Cattle and Pigs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Tylosin base (powder) 200,000 IU

1ml of solution contains 200 mg of tylosin activity corresponding to 200,000 IU

Excipients:
Benzyl alcohol (E1519) 40 µl

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection.

A clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Pigs (weighing more than 25 kg)

4.2 Indications for use, specifying the target species

Infections caused my microorganisms susceptible to tylosin.

Cattle (adult):
- Treatment of respiratory infections, metritis caused by Gram-positive micro-organisms, mastitis caused by *Streptococcus* spp., *Staphylococcus* spp., or *Mycoplasma* and interdigital necrobacillosis caused by *Fusobacterium necrophorum* i.e. panaritum or foot rot.

Calves:
- Treatment of respiratory infections and necrobacillosis (calf diphtheria caused by *Fusobacterium necrophorum)*.

Pigs:
- Treatment of enzootic pneumonia caused by *Mycoplasma hyopneumoniae*, haemorrhagic enteritis (Porcine proliferative haemorrhagic enteropathy due to *Lawsonia intracellularis*), erysipelas caused by *Erysipelothrix rhusiopathiae* and metritis.
- Treatment of arthritis caused by *Mycoplasma* and *Staphylococcus* spp.

4.3 Contraindications

Do not administer to horses.
Do not administer to chickens or turkeys.
Do not administer in cases of known hypersensitivity to tylosin, other macrolides or any of the excipients
Do not use in weaner pigs.

4.4 Special warnings for each target species

High *in-vitro* resistance has been demonstrated against European strains of *Brachyspira hyodysenteriae* implying that the product will not be sufficiently efficacious against swine dysentery.

4.5 Special precautions for use

(i) Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.
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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to tylosin and may decrease the effectiveness of treatment with other macrolide antibiotics due to the potential for cross resistance.

For administration by the intramuscular route only.
Where repeat injections are to be administered, use different sites for each injection.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals.

Care should be taken to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean running water.

Wash hands after use.

Tylosin may induce irritation. Macrolides, such as Tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to Tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided.

Do not handle the product if you are allergic to ingredients in the product.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Any direct or indirect (airborne) contact via the skin or mucous membranes should be avoided due to the risk of sensitisation.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, the following adverse reactions have been observed in animals administered tylosin at the recommended rate:

- Injection site reaction
- vulval swelling in cattle
- Oedema of the rectal mucosa, partial anal protrusion (rosebudding), erythema and pruritus in pigs
- Anaphylactic shock and death.

Blemishes may occur at the site of injection and can persist for up to 21 days following administration.

To avoid blemish at the site of injection pigs should not be slaughtered for human consumption for 21 days following last treatment.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not produced any evidence of teratogenic, foetoxic or maternotoxic effects. No studies have been conducted in the target species. Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Tylosin should be given by intramuscular injection at the following dose rates:

Cattle and Pigs: 5 to 10mg per kg bodyweight daily (2.5 to 5 ml solution for Injection per 100kg bodyweight).
The maximum treatment period is 3 days.

The maximum injection volume for pigs is limited to 1.3 ml per injection site.
The maximum injection volume for cattle is limited to 15 ml per injection site.

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

50ml and 100ml vials can only be broached a maximum of 80 times, 250ml and 500ml vials can only be broached a maximum of 45 times.

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

None

4.11 Withdrawal Period(s)

Cattle: Meat and offal - 28 days
Milk - 108 hours.

Pigs: Meat and offal - 14 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Macrolides, tylosin.

ATC vet code: QJ01FA90

5.1 Pharmacodynamic properties

Tylosin is a macrolide antibiotic with a pKa of 7.1. Tylosin is structurally similar to erythromycin.It is produced by *Streptomyces fradiae*. Tylosin has a low solublility in water. Tylosin exerts its antibiotic activity by a similar mechanism to other macrolides and lincosamides, i.e. by binding the 50 S fraction of the ribosomes resulting, in an inhibition of the synthesis of proteins. Tylosin has mainly a bacteriostatic activity. Tylosin has an antibiotic effect against Gram positive cocci (*Staphylococci*, *Streptococci*), Gram positive bacilli (*Trueperella* spp (formerly known as *Arcanobacterium* spp)., *Clostridium* spp., *Erysipelothrix*, *Actinomyces*), certain Gram-negative bacilles (*Histophilus* spp., (formerly known as *Haemophilus* spp) *Pasteurella* spp., *Mannheimia* spp.) and *Mycoplasma*.

Resistance of *Brachyspira hyodysenteriae* to tylosin has been reported.

5.2 Pharmacokinetic properties

Absorption: Following intramuscular injection the tylosin concentration reaches its maximum at 3-4 hours following administration.

Distribution:
The maximum concentration in milk of cattle and sows is 3-6 times higher than the blood concentration about 6 hours following injection. In bovine and porcine lungs maximum tylosin concentrations of 7-8 times higher than the maximum concentrations in serum were found at 6-24 hours following intramuscular injection. In cattle (whether in heat or not) the Mean Residence Time (MRT) in uterus secretions of tylosin injected by intravenous route at a dose rate of 10 mg/kg was about 6-7 times higher than the one measured in serum. This illustrates that in uterine secretions a single tylosin injection at a dose rate of 10 mg/kg during 24 hours can result in concentrations exceeding the MIC90 of tylosin for *Trueperella pyogenes* (formerly known as *Arcanobacterium* spp), one of the pathogens frequently isolated when metritis is diagnosed in cattle.

Elimination:
Tylosin is eliminated in unchanged form in bile and urine

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl acohol
Propylene glycol
Water for injection

6.2 Incompatibilities

Do not mix with other solutions, since this may cause precipitation of the active ingredient.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after first opening of the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Carton box containing 50ml, 100ml, 250ml and 500ml amber Type II glass vials sealed with chlorobutyl bungs and aluminium caps.
Carton box containing 50ml , 100ml 250ml and 500ml amber coloured PET vials sealed with chlorobutyl bungs and aluminium caps.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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(S)

VPA 10999/170/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st February 2014

10 DATE OF REVISION OF THE TEXT