Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylo 200 mg/ml solution for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:		
Tylosin base	200	mg/ml
(as Tylosin tartrate)		
Excipients:		
Benzyl alcohol	40.0	mg/ml

For a 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 and pigs.

4.2 Indications for use, specifying the target species

Treatment of infections of the respiratory, gastrointestinal and urogenital system, including infections of the skin and the soft tissues caused by tylosin-sensitive pathogenic germs.
Specific indications for use per species:
Cattle:
Bronchopneumonia
Pasteurellosis
Calf pneumonia (acute)
Footrot
Calf septicemia
Metritis

Swine:
Swine enzootic pneumonia (Mycoplasm infection)
Acute pneumonia
Atrophic rhinitis (*Bordetella bronchiseptica*, *Mycoplasma suis*, *Pasteurella*, *Haemophilus*, complex etiology).
Swine dysenteria (*Treponema hyodysenteriae*)
Erysipelas

4.3 Contraindications

Do not administer to horses.

4.4 Special warnings for each target species

Do not inject more than 10 ml of solution per injection site and use alternate sites for subsequent injection.

4.5 Special precautions for use

Special precautions for use in animals
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.

Special precautions to be taken by the person administering the medicinal product to animals
None

4.6 Adverse reactions (frequency and seriousness)

Local swelling at the injection site can occur. Erythema, oedoma of the rectal mucosa and diarrhoea may be observed in pigs.

4.7 Use during pregnancy, lactation or lay

Tylo 200 can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Tylosin antagonises many other antibiotics such as penicillins, aminoglycosides, chloramphenicol and lincosamides.

4.9 Amounts to be administered and administration route

10 mg/kg bodyweight i.e. 1 ml/20 kg bodyweight once or twice daily for 3 – 5 days, by deep intramuscular injection.

To ensure a correct dosage bodyweight should be determined as accurately as possible.

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

The therapeutic index of tylosin is very large. The risk of overdose is therefore very small. In case of high overdosage convulsic symptoms can be observed. The treatment is symptomatically.

4.11 Withdrawal Period(s)

Meat: 28 days
Milk: 7 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group : Macrolides.
ATCvet code : QJ01FA90.

5.1 Pharmacodynamic properties

Tylo 200 contains tylosin tartrate as active ingredient. Tylosin is an antibiotic belonging to the group of macrolides; the tartrate salt is very soluble in water. Tylosin interferes with the microbial protein synthesis by inhibiting the enzymatic activity of peptidyltransferase in the ribosomes at the ribosomal 50 S subunit. This causes a bacteriostasis.

Tylosin is a broad spectrum antibiotic, active against Gram-positive cocci and bacteria (staphylococci, streptococci, Corynebacterium diphteriae), mycoplasmas (*Mycoplasma bovis*, *Mycoplasma hyopneumoniae*), ureaplasmas and *Treponema hyodysenteriae*.

5.2 Pharmacokinetic properties

Tylosin tartrate is absorbed quite quickly from the injection site after intramuscular administration. Tylosin is lipophilic, diffuses very well in the lungs, in the intestinal tissues and in the milk. It is mainly excreted in the bile.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Benzyl alcohol
Disodium edetate
Water for injections

6.2 Incompatibilities

Tylosin is incompatible with sodium heparine, hydrocortisone, streptomycin and tetracyclines.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).
Protect from light.

6.5 Nature and composition of immediate packaging

Round Type II amber glass vials of 100 ml with bromobutyl rubber stopper, sealed with aluminium cap.

The vials are packed in a polystyrene box, 12 vials of 100 ml per box, wiht 12 package leaflets.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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St. Lenaartseweg 48
B-2320 Hoogstraten
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10981/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

June 2012