# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan 200, 200 mg/ml Solution for Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**

Tylosin activity 200 mg

**Excipients:**

Benzyl alcohol 40 mg

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 and pigs.

### 4.2 Indications for use, specifying the target species

Tylan 200 is indicated in all conditions associated with bacteria sensitive to tylosin which includes organisms in the following genera:

| | | |
|---|---|---|
| Streptococcus | Campylobacter | Chlamydia |
| Bacillus | Spirochaetes | |
| Staphylococcus | Mycoplasma | |
| Corynebacterium | Fusiformis | |
| Clostridium | Pasteurella | |
| Erysipelothrix | | |

Tylan 200 has been successfully used in respiratory and genito-urinary tract infections, otitis, cellulitis and secondary bacterial conditions associated with virus disease or post operative infections.

Specific disease entities treated successfully with Tylan include swine dysentery, erysipelas and enzootic pneumonia in pigs, foul in the foot, mastitis and calf pneumonia in cattle.

## 4.3 Contraindications

Tylan 200 should not be given to chickens or turkeys.

Do not administer to horses or other equines in which injection of tylosin may be fatal.

## 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

### (i) 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 epidemiological information.

For administration by the intramuscular route only.
Use different injection sites for repeat injections.

### (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.

If accidental self-injection occurs, seek medical attention immediately.

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.

**(iii) Other precautions**

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

## 4.6 Adverse reactions (frequency and seriousness)

Possible adverse reactions attributed to the product when used as recommended and their frequency are: In very rare cases the following have been observed;

- swelling/inflammation at the site of injection,
- vulvular swelling in cattle,
- oedema of the rectal mucosa, partial anal protrusion ('rosebudding'), erythema and pruritus in pigs.
- Anaphylactic shock and death.

## 4.7 Use during pregnancy, lactation or lay

No adverse effects to tylosin have been seen in fertility, multi-generation or teratology studies.

## 4.8 Interaction with other medicinal products and other forms of interaction

None observed.

## 4.9 Amounts to be administered and administration route

Tylan 200 should be given by intramuscular injection at the following dose rates:
Cattle and calves: 4 to 10 mg per kg bodyweight daily.
Pigs: 2 to 10 mg per kg bodyweight daily.
If there is no response to treatment in 3 days, diagnosis and treatment should be reassessed.
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.

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

Pigs and calves: Intramuscular injection of 30 mg/kg bodyweight per day (three times maximum recommended dose) for five days produced no adverse effects.
The $LD_{50}$ for subcutaneous injection of tylosin in mice is estimated to be >2500 mg/kg bodyweight.

### 4.11 Withdrawal period(s)

Pigs: Meat - 9 days
Cattle: Meat - 28 days
Milk - 108 hours

With cows milked twice daily, milk for human consumption may be taken only from 108 hours i.e. at the 9th milking) after the last treatment. With other dosing routines, the basis of the veterinary surgeons advice should be that milk may be taken for human consumption only after the same period from the last treatment (i.e. with three times a day milking, milk for human consumption may be taken only from 108 hours i.e. at the 14th milking).

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Macrolides
ATC vet code: QJ01FA90

### 5.1 Pharmacodynamic properties

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms.

The tylosin spectrum of activity includes Gram-positive bacteria, some Gram-negative strains such as Pasteurella, and Mycoplasma spps at concentrations of 16µg/ml or less. It is not generally active against anaerobes.

### 5.2 Pharmacokinetic particulars

Absorption: Following intramuscular injection, tylosin blood levels peak 1-2 hours post-injection. Duration of activity is approximately 12 hours.

Distribution, Biotransformation and Elimination: Tylosin levels of 1.4 to 1.6 and 2.2 to 6.7 µg/ml were recorded in serum and lung tissue respectively following intramuscular injection of 8.8 mg/kg bodyweight in pigs. Measurable amounts of tylosin were still present in both serum and lung tissue at 12 hours post injection. Tylosin concentrations were greater in lung tissue than serum at all sample times.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzyl alcohol
Propylene glycol
Water for Injection

### 6.2 Incompatibilities

This veterinary medicinal product must not be mixed with other veterinary medicinal products as this may cause precipitation of the active ingredient.

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
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

100 ml or 250 ml clear glass vials sealed with butyl rubber stoppers and aluminium overseals. Each vial is packed into a carton.

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 products should be disposed of in accordance with national requirements.

## 7. MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

## 8. MARKETING AUTHORISATION NUMBER

Vm 43877/4004

## 9. DATE OF FIRST AUTHORISATION

26 May 2016

## 10. DATE OF REVISION OF THE TEXT

May 2016

**Approved: 26/05/2016**