

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tyloject 200 mg/ml Solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance

Tylosin tartrate 200 mg

### Excipients

Benzyl alcohol 10 mg

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

Pigs

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

The product is specifically formulated for the treatment and prevention of infections caused by organisms sensitive to Tylosin e.g. *Spirochaetes*, *Leptospira*, *Actinomyces*, *Mycoplasmas*, *Haemophilus pertussis*, *Moraxella bovis*, *Streptococci spp.*, *Neisseria spp.* and some Gram negative bacteria. It is also effective against some *Mycoplasmas*, *Chlamydiae* and *Rickettsiae*.

The product is recommended for use in the treatment of a wide range of common respiratory and genito-urinary tract, otitis, cellulitis and secondary bacterial conditions associated with viral disease or postoperative infections in pigs.

### 4.3 Contraindications

Do not use in very young animals. This product contains Benzyl Alcohol, which has been documented to cause adverse reactions in neonates.

### 4.4 Special warnings for each target species

Oedema of the anal mucosa, partial anal protrusion, erythema and pruritis have occasionally been reported following medication in pigs. This product contains Benzyl Alcohol which has been documented to cause adverse reactions in neonates. Hence the product should not be used in young animals.

## 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 veterinary medicinal product to animals

Avoid direct contact with the product.

Use gloves when administering the product.

Seek medical advice if symptoms such as skin rash, swelling of face, lips etc occurs.

## 4.6 Adverse reactions (frequency and seriousness)

Toxicity and side effects are uncommon although pain and swelling may occur at the injection sites.

Tylosin may cause oedema of the rectal mucosa, mild anal protrusion with diarrhoea after a few days and pruritis.

Generally, these adverse effects are rare in occurrence.

## 4.7 Use during pregnancy, lactation or lay

The product may be used during pregnancy and lactation.

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

The product should not be administered with chloramphenicol or the lincosamides since they may compete for the same 50S ribosomal site.

Do not mix with other products.

## 4.9 Amounts to be administered and administration route

The product is only for administration by intramuscular injection in the target species.

10 mg/ kg bw equivalent to 0.5 ml/10 kg bw daily for up to 3 days.

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

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

Acute, subacute and chronic toxicity have shown that Tylosin has a wide margin of safety. To avoid any overdose, inject recommended volumes only.

## 4.11 Withdrawal Period(s)

Meat and offal: 7 days after last treatment

Milk : not applicable

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; macrolides

ATCvet Code: QJ01FA90

## 5.1 Pharmacodynamic properties

Tylosin is a bacteriostatic antibiotic belonging to the macrolide group. It acts by interfering with protein synthesis by reversible binding to the 50S subunit of the ribosome. It binds at the donor site, thus preventing the translocation necessary to keep the peptide chain growing.

## 5.2 Pharmacokinetic properties

Plasma concentrations are detectable within 30 minutes and generally reach a peak at this time. Peak plasma levels are on average above 2.29 microg/ml, after 30 minutes following a single injection. These decrease to < 0.2 microg/ml after 24 hours. Tylosin is widely distributed in all tissues with concentrations about the same as in plasma. It actually accumulates within many cells, including macrophages. It is particularly concentrated in the spleen, liver kidneys and the lungs. 75% of the dose is plasma bound. Biotransformation is usually extensive but the relative proportion depends on the route of administration. Tylosin is excreted mainly in the bile (>60%) and a smaller proportion via the urine (<10%).

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium citrate  
Benzyl alcohol  
Propylene glycol  
Water for injections

### 6.2 Incompatibilities

Incompatible with chloramphenicol or lincosamides.

### 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: 7 days

### 6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

### 6.5 Nature and composition of immediate packaging

100 ml amber Type II glass vials closed with bromobutyl rubber bung and aluminium seal, containing a clear yellow solution.  
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 product should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Franklin Pharmaceuticals (Ireland) Limited  
Athboy Road  
Trim  
County Meath

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10976/004/001

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30<sup>th</sup> September 2008

**10 DATE OF REVISION OF THE TEXT**

8<sup>th</sup> June 2010