

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylo 200 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

200 mg Tylosin base as Tylosin tartrate

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Propylene glycol	
Benzyl alcohol	40.0 mg
Disodium edetate	
Water for injections	

A clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each 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 septicaemia
Metritis

Swine:

Swine enzootic pneumonia (Mycoplasma infection)
Acute pneumonia
Atrophic rhinitis (*Bordetella bronchiseptica*, *Mycoplasma suis*, *Pasteurella*, *Glaeserella*, complex aetiology).
Swine dysentery (*Brachyspira hyodysenteriae*)
Erysipelas

3.3 Contraindications

Do not administer to horses.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal 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:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle and pigs:

Undetermined frequency (cannot be estimated from the available data)	Injection site swelling ¹ ; Perianal inflammation ² , Diarrhoea ² ; Rectal oedema ² ; Erythema ² .
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¹ Localised.

² In pigs.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Intramuscular use.

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, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days

Milk: 7 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FA90

4.2 Pharmacodynamics

This veterinary medicinal product 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 diphtheriae*), mycoplasmas (*Mycoplasma bovis*, *Mycoplasma hyopneumoniae*), ureaplasmas and *Brachyspira hyodysenteriae*.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Store in a refrigerator (2°C – 8°C).

Protect from light.

5.4 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, with 12 package leaflets.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela nv

7. MARKETING AUTHORISATION NUMBER(S)

VPA10981/004/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

17/11/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](#)

(<https://medicines.health.europa.eu/veterinary>).