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 200 mg/ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol	40 mg/ml
Propylene Glycol	
Water for Injections	

A sterile yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in all conditions associated with bacteria sensitive to tylosin which includes organisms in the following genera:

Streptococcus	*Campylobacter*
Bacillus	*Spirochaetes*
Staphylococcus	*Chlamydia*
Corynebacterium	*Fusiformis*
Clostridium	*Pasteurella*
Erysipelothrix	

The veterinary medicinal product 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 the veterinary medicinal product include Swine Dysentery, Erysipelas and Enzootic Pneumonia in pigs, foul in the foot, mastitis and calf pneumonia in cattle.

For the treatment and metaphylaxis of enzootic pneumonia, swine dysentery and other scours caused by organisms sensitive to tylosin, in pigs.

For the treatment and metaphylaxis of pneumonia in cattle associated with mycoplasmata and *Pasteurella multocida* sensitive to tylosin.

The presence of the disease in the group must be established before the veterinary medicinal product is used.

3.3 Contraindications

Do not use in chickens or turkeys.
Do not use in equine animals. Injection of Tylosin in equines has been fatal.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

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. Whenever possible the veterinary medicinal product should only be used on the basis of susceptibility testing. Use of the veterinary medicinal 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 potential of cross-resistance.
The efficacy data do not support the use of tylosin for the treatment of bovine mastitis caused by *Mycoplasma* spp.

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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

None known.

3.6 Adverse events

Cattle and pigs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site reaction Rectal prolapse[1] Anaphylactic shock, Rectal oedema[1], Vulvar oedema[2], Erythema[1], Pruritus[1] Death

[1] In pigs.
[2] In cattle.

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use.
Inject intramuscularly only. A dry hypodermic needle and syringe should be used where possible. It is advisable to alternate the injection site when repeated daily doses are given.

Cattle and pigs: 10 mg per kg body weight (1 ml per 20 kg) daily.

The veterinary medicinal product should be given by intramuscular injection at a dose rate of 10 mg/kg bodyweight.

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

In pigs do not administer more than 5 ml per injection site.

Where repeat injections are to be administered, use different sites for each injection.

The stopper of the veterinary medicinal product may be punctured up to a maximum of 30 times.

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the veterinary medicinal product should be discarded. The administration of antibiotics may result in the over-growth of non-susceptible organisms. If new infections due to bacteria or fungi appear during treatment with this drug, appropriate measures should be taken. If there is no response to therapy in 3 days, diagnosis and treatment should be reassessed.

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

Shock and death may occur on rare occasions following overdose in piglets and calves.

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

Cattle:
Meat and offal: 28 days.
Milk: 96 hours.

Pigs:
Meat and offal: 16 days.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01FA90

4.2 Pharmacodynamics

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, and some Gram-negative strains such as Pasteurella, at concentrations of 16 µg/ml or less.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product with any other solutions, since this may cause precipitation of the active ingredient.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 90 days.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

100 ml clear type II glass vial sealed with a grey butyl rubber bung with aluminium overseal. Each vial is packed into a carton.

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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22020/033/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

17/07/2025

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).