Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan 200, 200 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Tylosin (as the base) 200 mg/ml
Excipient
Benzyl Alcohol 40 mg/ml
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A sterile yellow solution

4 CLINICAL PARTICULARS

4.1 Target Species

Tylan 200 mg/ml Solution for Injection is indicated for use in cattle and pigs.

4.2 Indications for use, specifying the target species

TYLAN 200 mg/ml Solution for Injection is indicated in all conditions associated with bacteria sensitive to tylosin which includes organisms in the following genera:

Streptococcus	Campylobacter
Bacillus	Spirochaetes
Staphylococcus	Fusiformis
Corynebacterium	Pasteurella
Clostridium	Chlamydia
Erysipelothrix	

TYLAN 200 mg/ml Solution for Injection 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.
For the prevention and control of enzootic pneumonia, swine dysentery and other scours caused by organisms sensitive to tylosin, in pigs.
For the control of pneumonia in cattle associated with mycoplasmata and *Pasteurella multocida* sensitive to tylosin.

4.3 Contraindications

Tylan 200 should not be given to chickens or turkeys.
Do not use in animals with known hypersensitivity to the active ingredients.
Do not use in equine animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Use of this 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 product should only be used on the basis of susceptibility testing. Use of the 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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, the following adverse reactions have been observed in animals administered tylosin at the recommended rate:

- Injection site reaction
- vulvular swelling in cattle,
- oedema of the rectal mucosa, partial anal protrusion (rose budding), erythema and pruritus in pigs.
- anaphylactic shock and death.

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

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 interactions

None observed.

4.9 Amounts to be administered and administration route

Tylan 200 mg/ml Solution for Injection 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.

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

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

4.11 Withdrawal period(s)

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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Macrolides, Licosamides and Streptogramins.
ATCvet 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 at concentrations of 16µg/ml or less.

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 8.8mg/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 Injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf-life after first opening 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

Carton containing 100 ml clear type II glass vials, each of which is sealed with a grey butyl rubber bung with aluminium overseal, packed in a carton.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/033/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 20 February 2009

10 DATE OF REVISION OF THE TEXT

June 2020