1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Tylosin 200 mg
(equivalent to 233 mg 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**
Benzyl alcohol	40 mg
Sodium metabisulphite	
Disodium edetate	
Sodium citrate	
Propylene glycol	
Water for injections	

A limpid, yellow coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

Cattle:
Respiratory tract infections caused by *Mycoplasma* spp..
Metritis caused by *Corynebacterium pyogenes*.
Mastitis caused by *Streptococcus* spp. and *Staphylococcus* spp..

Pigs:
Arthritis caused by *Mycoplasma hyosynoviae* and *Staphylococcus* spp..
Pneumonia caused by *Mycoplasma* spp. and *Corynebacterium pyogenes*.
Erysipylas caused by *Erysipelothrix rhusiopathiae*.
Dysentery associated with *Treponema hyodysenteria*.

3.3 Contraindications

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 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:
Contact dermatitis due to tylosin is reported in the literature.
Wash hands after use.

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

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Injection site reaction

Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site reaction, injection site oedema, injection site pruritus Rectal oedema[1] Anal prolapse[2]

[1] of the mucosa.
[2] mild protrusion.

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 and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Antagonism with penicillins and cefalosporins.

3.9 Administration routes and dosage

Intramuscular use:

Pigs: 10 mg per kg bodyweight daily for 3 days.
Cattle: 10 mg per kg bodyweight daily for 3 – 5 days.

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)

Pigs have been reported to react to injection by developing oedema, pruritis, oedema of rectal mucosa and mild anal protrusion.

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: 35 days.
Milk: 96 hours (at the eighth milking in cows milked twice daily).

Pigs:
Meat and offal: 21 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01FA90

4.2 Pharmacodynamics

Tylosin is a macrolide antibiotic active mainly against Gram-positive bacteria, but it is also active against *Mycoplasma*, *Erysipelothrix*, *Spirochaetes*, *Corynebacterium*, and certain Gram-negative bacteria.

4.3 Pharmacokinetics

Following intramuscular administration in pigs and cattle peak plasma concentrations were reached after 1 - 2 hours. Tylosin is well distributed to organs and tissues. Following intramuscular administration, the elimination half-life was 2-3 hours in cattle but in pigs could exceed 24 hours. In milk and lung tissue tylosin concentrations exceeded those in plasma. Binding is approximately 40%. Tylosin is excreted mainly through the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 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).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

100 ml amber vials, siliconized glass type II, with butyl rubber stoppers and non reusable aluminium closures.

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

Absorb spills with an inert material.
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

Alfasan Nederland B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10980/005/001

8. DATE OF FIRST AUTHORISATION

30/09/2008

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

23/06/2025

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).