TILOCEN 200000 IU/ml
Solution for Injection

STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:

Tylosin tartrate ..... 200000 IU

Excipients:

Benzyl alcohol ..... 20 mg (as preservative)

Clear yellow solution.

INDICATIONS

Treatment of infections caused by microorganisms sensitive to tylosin:

Bovine: Respiratory infections caused by *Pasteurella multocida* and *Arcanobacterium pyogenes.* Metritis caused by *Arcanobacterium pyogenes.* Hoof infections caused by *Fusobacterium necrophorum.*

Porcine: Respiratory infections caused by *Mycoplasma hyopneumoniae.* Mycoplasma arthritis caused by *Mycoplasma hyosynoviae.*

CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to tylosin, other macrolides or some of the excipients. Do not use in animals with kidney or liver failure.

Do not use in horses or other equines as the tylosin injection could be fatal.

Do not use in suspected cases of cross-resistance to other macrolides.

SIDE EFFECTS

Frequent local reactions with necrosis and haemorrhage have been observed. Allergic reactions, anaphylactic shock, and death have rarely been observed. In pigs, oedema in the rectal and vaginal mucosa and in the vulva, rectal prolapse, diarrhoea, erythema and itching all over the skin have been observed. In bovine, an increase of the heart rate, vulvar tachypnea and swelling have been observed. Allergic reactions, anaphylactic shock and death have been rarely observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

TARGET SPECIES

Bovine and porcine

DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINITRATION

Administration via deep intramuscular injection.

Bovine: 10000 – 20000 IU of Tylosin Tartrate/kg b.w./day (equivalent to 0.5 – 1 ml/ 10 kg b.w./day), for 5 consecutive days.

Porcine: 10000 – 20000 IU of Tylosin Tartrate/kg b.w./day (equivalent to 0.5 – 1 ml/ 10 kg b.w./day), for 5 consecutive days. The treatment will not last longer than 5 days.

ADVICE ON CORRECT ADMINISTRATION

Respect a maximum volume per injection point of: **Bovine**: 15 ml **Porcine**: 5 ml

Allow sufficient separation between injection points when several administration sites are necessary. Massage lightly the injection point. The injection is to be administered preferably to the neck muscles.

The animals' weight must be determined as exactly as possible to avoid insufficient dosage.

WITHDRAWAL PERIOD

Bovine: Meat: 24 days Milk: 108 hours Porcine: Meat: 13 days.

SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer packaging in order to protect from light. Do not store above 30º.

Shelf-life after first opening the immediate packaging: 28 days at not above 30ºC.

SPECIAL WARNINGS

Special warnings for each target species:

Do not administer to suckling pigs of less than 3 kg, unless it is possible to measure the dose with great precision.

Special precautions for use in animals:

Good clinical practice requires basing treatment on sensitivity tests of the bacteria isolated from diseased animals. If this is not possible, treatment should be based in local epidemiological information (regional, farm level) on the sensitivity of the different strains of the bacterial species usually involved in the infectious process.

Using the medicinal product in conditions different to those recommended in the Data Sheet may result in an increase of the prevalence of tylosin resistant bacteria and consequently reduce the efficiency of treatments with other macrolides as a consequence of the appearance of crossed resistances.

Special precautions to be taken by the person administering the medicinal product to the animals:

Tylosin may cause irritation. Macrolides such as tylosin may also cause hypersensitivity (allergy) after being injected, inhaled, ingested o touching the skin or the eyes. Hypersensitivity may include cross reactions with other macrolides and vice versa. Occasionally allergic reactions to these substances may be serious, therefore, direct contact must be avoided. Do not handle the medicinal product if you are allergic to any of its ingredients. If symptoms appear after exposure, such as a rash, consult a doctor and show him the package leaflet or the label. Inflammation of the face, lips or eyes or breathing difficulty are very serious signs that require urgent medical attention. Avoid contact with eyes and skin. If this occurs, wash the affected area with plenty of water. Handle the medicinal product with care to avoid accidental self-injection. In the event of accidental self-injection, see a doctor immediately and show him the information leaflet or label. Do not smoke, eat or drink while handling the medicinal product. Wash hands after the use.

Use during pregnancy, lactation or lay**:** No adverse effects described during these periods.

Interaction with other medicinal products and other forms of interaction: Florfenicol, lincosamides and other antibacterial macrolides, as they have a similar reaction to the tylosin, interact when competing for the union in the subunit 50S; therefore it is not recommended to use them simultaneously.

Overdose (symptoms, emergency, procedures, antidotes), if necessary: Given the administering method and the wide security range of the tylosin, it is difficult to cause an overdose intoxication.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

OTHER INFORMATION

Pharmacotherapeutic group: Antibacterials for systemic use. Macrolides, lincosamides and streptogramins.
ATC Vet code: QJ51FA90

Pharmacodynamic properties

Tylosin is an antibacterial compound that belongs to the macrolides family, it is bacteriostatic with the usual dose and bactericidal in large doses. It penetrates into the bacteria by passive diffusion and inhibits the synthesis of bacterial proteins when performing the union with the ribosome subunit 50S.
The inhibition of protein synthesis induced by tylosin prevents, in principle, the bacterial metabolism, providing tylosin the features of a time-dependent bacteriostatic agent.
The tylosin has a post.antibiotic effect.
Active against:
Gram-negative bacteria: *Pasteurella multocida* and *Fusobacterium necrophorum*.
Gram-positive bacteria: *Arcanobacterium pyogenes.*
Mycoplasmas: *Mycoplasma hyopneumoniae* and *Mycoplasma hyosynoviae.*
The main resistance mechanism to tylosin is caused by alterations of the bacterial 23S ribosomal RNA, although others have been described in the subunit 50S and in the plasmids.
There are cross resistances with macrolides, lincosamides and streptogramins (MLS_B).

Pharmacokinetic properties

Administered parenterally, it reaches the maximum concentration in blood within 3-4 hours. The tylosin joins bovine plasma proteins in a 40%. The levels in plasma are very low in comparison to those in tissues. It is metabolized in the liver. Tylosin is excreted in the urine and the bile in its non-altered form.

Pack size:

Box containing 1 vial of 100 ml.
Box containing 1 vial of 250 ml.
Not all pack sizes may be marketed.

For animal treatment only. To be supplied only on veterinary prescription.
Keep out of the sight and reach of children.
“Jauhi ubat dari kanak-kanak”
Ubat Terkawal

DATE OF REVISION OF LEAFLET

February 2023

MARKETING AUTHORISATION HOLDER

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