[Version 9,10/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylolab tartrate 200,000 IU/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Tylosin tartrate 200,000 IU

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 (E 1519)	5 mg
Propylene glycol	
Sodium citrate	
Water for injections	

Clear, yellow or yellow-orangish solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

Cattle:
- For the treatment of respiratory infections caused by *Pasteurella multocida, Trueperella pyogenes* or *Fusobacterium necrophorum.*
- For the treatment of foot infections caused by *Fusobacterium necrophorum.*

Pigs:
- For the treatment of respiratory infections caused by *Pasteurella multocida* or *Mycoplasma hyopneumoniae*.
- For the treatment of mycoplasmal arthritis caused by *Mycoplasma hyosynoviae*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other macrolides or to any of the excipients.
Do not use in animals with renal and /or liver failure.
Do not administer to horses or other equines in which injection of tylosin may be fatal.
Do not use in suspected cases of cross-resistance to other macrolides

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Cross-resistance has been shown between tylosin and other macrolides or lincosamides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to macrolides or lincosamides because its effectiveness may be reduced.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach

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

Macrolides, such as tylosin, can cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eyes. Hypersensitivity to tylosin may lead to cross- reactions with other macrolides and vice versa. Sodium citrate, benzyl alcohol and propylene glycol can also cause hypersensitivity reactions. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided. Do not handle the medication if you are allergic to any of the veterinary medicinal product ingredients
If you develop symptoms following exposure such as skin rash, seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
The veterinary medicinal product may cause irritation to the eyes and skin.
Avoid contact with eyes and skin. If this occurs, wash the area thoroughly with water.
Care must 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.
Do not smoke, eat or drink while handling the medication.
Wash hands after use.

3.6 Adverse events

Cattle and pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site reactions [1]with necrosis and hemorrhage.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reactions, anaphylactic shock and death. In cattle there has been increased pulse rate, tachypnea and swollen vulva In pigs, vulvar oedema and rectal oedema, rectal prolapse, diarrhea, erythema and general pruritus in all the skin

1-can persist for up to 21 days following administration

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation
Laboratory studies in mice and rats have not produced any evidence of teratogenic, fetotoxic, maternotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent use of florfenicol, lincosamides and other macrolide antibacterials that have a similar action to tylosin, interacting by competing for binding to the 50S subunit, is not recommended.

3.9 Administration routes and dosage

Route of administration: For deep intramuscular injection.

Cattle: 10,000-20,000 UI of tylosin tartrate/kg bodyweight per day (equivalent to 0.5-1 ml of the veterinary medicinal product/10 kg bodyweight /day) during 5 consecutive days.
Pigs: 10,000-20,000 UI of tylosin tartrate/kg bodyweight per day (equivalent to 0.5-1 ml of the veterinary medicinal product/10 kg bodyweight /day) during 5 consecutive days.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.
The following maximum volumes should not be exceeded per injection site:

Pigs: 5 ml
Cattle: 25 ml

Provide adequate spacing between injection sites when multiple points of treatment are necessary.
Give a light massage of the injection site.
The cap may be safely punctured up to 34 times for 100 ml vials and 84 times for the 250 ml vials.

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

Pigs and calves: Intramuscular injection of 30,000 UI/kg bodyweight per day for five days produced no adverse effects.

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

Exclusive administration by the veterinarian or under his supervision.

3.12 Withdrawal periods

Pigs: Meat and offal: 21 days.
Cattle: Meat and offal: 33 days.
Milk: 5 days (120 hours).

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01FA90

4.2 Pharmacodynamics

Macrolides are bacteriostatic acting antibiotics and inhibit essential protein biosynthesis by virtue of their selective binding to bacterial ribosomal RNA. They act by stimulating the dissociation of peptidyl-tRNA from the ribosome during the translocation process.

Tylosin is active against:

- Bacteria Gram (+) :

Trueperella pyogenes

- Bacteria Gram (-):

Fusobacterium necrophorum
Pasteurella multocida.

- Mycoplasmas:

Mycoplasma hyopneumoniae
Mycoplasma hyosynoviae.

Resistance to macrolides can develop by mutations in genes encoding ribosomal RNA (rRNA) or some ribosomal proteins; by enzymatic modification (methylation) of the 23S rRNA target site, generally giving rise to cross-resistance with lincosamides and group B streptogramins (MLS_B resistance); by enzymatic inactivation; or by macrolide efflux. MLS_B resistance may be constitutive or inducible. Resistance may be chromosomal or plasmid-encoded and may be transferable if associated with transposons, plasmids, integrative and conjugative elements. Additionally, the genomic plasticity of *Mycoplasma* is enhanced by the horizontal transfer of large chromosomal fragments."

4.3 Pharmacokinetics

Following intramuscular injection, the tylosin concentration in blood reaches its maximum at 3-4 hours post injection. Plasma protein binding is 40% in pigs and cattle. Plasma levels are low compared with tissues levels. It is metabolised in the liver. It is excreted unaltered through bile and urine.

Environmental properties

Tylosin is persistent in some soils.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

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: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (+2ºC to +8ºC).

5.4 Nature and composition of immediate packaging

Nature of the container
Amber type II glass vials containing 100 mL and 250 mL veterinary medicinal product, closed with a chlorobutyl stopper and aluminium caps.

Pack sizes
Box with 1 vial of 100 ml
Box with 10 vial of 100 ml
Box with 1 vial of 250 ml
Box with 10 vial of 250 ml
Box with 20 vial of 250 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Labiana Life Sciences, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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).