ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with vial(s) of 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylolab tartrate 200,000 IU/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contain:
Tylosin tartrate 200,000 IU

3. PACKAGE SIZE

1 x 100 ml
1 x 250 ml
10 x 100 ml
10 x 250 ml
20 x 250 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For deep intramuscular injection.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp: {month/year}
Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, SA

14. MARKETING AUTHORISATION NUMBERS

Vm 32112/3001

15. BATCH NUMBER

Lot {number}

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16. SPECIAL WARNING(S) IF NECESSARY

'Macrolides, such as tylosin may occasionally cause severe allergic reactions. See package leaflet for user warnings.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylolab tartrate 200,000 IU/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contain:
Tylosin tartrate 200,000 IU

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp: {month/year}
Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, SA

9. BATCH NUMBER

Lot {number}

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B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tylolab tartrate 200,000 UI/ml solution for injection

2. Composition

Each ml contains:
Active substance:
Tylosin tartrate 200,000 IU

Excipients:
Benzyl Alcohol (E-1519): 5 mg

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

3. Target species

Cattle and pigs.

4. Indications for use

Cattle:
- Respiratory infections caused by *Pasteurella multocida, Trueperella pyogenes* or *Fusobacterium necrophorum.*
- Foot infections caused by *Fusobacterium necrophorum.*

Pigs:
- Respiratory infections caused by *Pasteurella multocida* or *Mycoplasma hyopneumoniae*.
- Mycoplasmal arthritis caused by *Mycoplasma hyosynoviae*

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, other macrolides or to any of the excipient.
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.

6. Special warnings

Special precautions for safe use in the target species:
Cross-resistance has been shown between tylosin and other macrolides or lincosamides. Use of the 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 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 the 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 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.

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.

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.

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

Special restrictions for use and special conditions for use:
This veterinary medicinal product if for administration only by a veterinarian or under their supervision.

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

7. Adverse events

Target species: 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

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 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 product/10 kg bodyweight /day) during 5 consecutive days.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

The following maximum volumes should not be exceeded per injection site:
Pigs: 5 ml
Cattle: 25 ml

9. Advise on correct administration

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.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (+2ºC to +8ºC).

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of in wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 32112/3001

Package 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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.
(https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release.
Labiana Life Sciences SA - Venus 26 - 08228 Terrassa (Barcelona) - Spain.

Local representatives and contact details to report suspected adverse reactionsCross Vetpharm Group UK Ltd. (T/A Bimeda), Unit 2,
Bryn Cefni Industrial Park, Llangefni, Anglesey, LL77 7XA,
United KingdomTel: 01248 725400 e-mail: uksales@bimeda.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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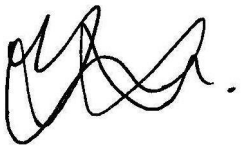

Approved: 28 September 2023