

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box with vial(s) of 20 ml, 50 ml, 100ml and 250 ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Labixxin 100 mg/ml solution for injection for cattle, pigs and sheep  
Tulathromycin

**2. STATEMENT OF ACTIVE SUBSTANCES**

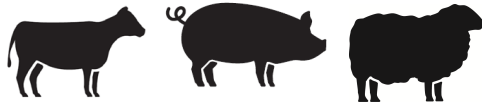
Each ml contains:  
Tulathromycin 100 mg

**3. PACKAGE SIZE**

1 x 20 ml  
1 x 50 ml  
1 x 100 ml  
1 x 250 ml  
12 x 20 ml  
12 x 50 ml  
10 x 100 ml  
10 x 250 ml

**4. TARGET SPECIES**

Cattle, pigs and sheep



**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Cattle: For subcutaneous use.  
Pigs and sheep: For intramuscular use.  
Read the package leaflet before use.

**7. WITHDRAWAL PERIOD(S)**

Withdrawal periods:  
Meat and offal:  
Cattle: 22 days.  
Pigs: 13 days.  
Sheep: 16 days.  
Not authorised for use in lactating animals producing milk for human consumption.

Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use by: ....

**9. SPECIAL STORAGE PRECAUTIONS**

**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, S.A.

**14. MARKETING AUTHORISATION NUMBER(S)**

**XXXXXX**

**17. BATCH NUMBER**

<Lot>{number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**100 ml and 250 ml Vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

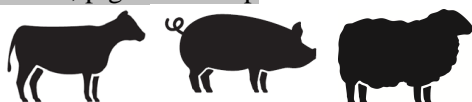
Labixxin 100 mg/ml solution for injection for cattle, pigs and sheep.  
Tulathromycin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:  
Tulathromycin 100 mg

**3. TARGET SPECIES**

Cattle, pigs and sheep



**4. ROUTES OF ADMINISTRATION**

Cattle: SC.  
Pigs and sheep: IM.  
Read the package leaflet before use.

**5. WITHDRAWAL PERIOD(S)**

Withdrawal periods:  
Meat and offal:  
Cattle: 22 days.  
Pigs: 13 days.  
Sheep: 16 days.  
Not authorised for use in lactating animals producing milk for human consumption.  
Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

**6. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use by....

**7. SPECIAL STORAGE PRECAUTIONS**

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Labiana Life Sciences, S.A.

**9. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**20 ml and 50 ml Vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Labixxin 100 mg/ml solution for injection for cattle, pigs and sheep.  
Tulathromycin



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Each ml contains:  
Tulathromycin 100 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}  
Once broached use by: ....