

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (100 ml / 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES**Each ml contains:**

Tulathromycin 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Cattle, pigs, and sheep.

6. INDICATION(S)**7. METHOD AND ROUTES OF ADMINISTRATION**

Cattle: For subcutaneous use.

Pigs and sheep: For intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)**Withdrawal periods:**

Cattle (meat and offal): 22 days.

Pigs (meat and offal): 13 days.

Sheep (meat and offal): 16 days.

Not authorised for use in 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use by:

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

11. SPECIAL STORAGE CONDITIONS**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MEVET S.A.U.

Polígono Industrial El Segre, p. 409-410

25191 Lleida

Spain

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (100 ml / 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Tulathromycin 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Cattle, pigs, and sheep.

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Cattle: For subcutaneous use.

Pigs and sheep: For intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle (meat and offal): 22 days.

Pigs (meat and offal): 13 days.

Sheep (meat and offal): 16 days.

Not authorised for use in 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use by:

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

11. SPECIAL STORAGE CONDITIONS**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY****13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

MEVET S.A.U.

Polígono Industrial El Segre, p. 409-410

25191 Lleida

Spain

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}