

*[Version 8.2,01/2021]*

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box (100 ml / 250 ml)**

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

TROXXAN 100 mg/ml solution for injection for cattle, pigs and sheep  
tulathromycin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substance:**

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 within 28 days

Once opened use by...

**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.

**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**

laboratorios syva, s.a.u.  
Avda. Párroco Pablo Díez,  
49-57 (24010) León  
Spain

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

<To be completed in accordance to National Authorisation after conclusion of the DC/MR phase>.

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Glass vial (100 ml / 250 ml)**

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

TROXXAN 100 mg/ml solution for injection for cattle, pigs and sheep  
tulathromycin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substance:**

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: SC.

Pigs and sheep: IM.

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 within 28 days

Once opened use by...

**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.

**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**

laboratorios syva, s.a.u.  
Avda. Párroco Pablo Díez,  
49-57 (24010) León  
Spain

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

<To be completed in accordance to National Authorisation after conclusion of the DC/MR phase>.

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}