

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

{NATURE/TYPE} 100 and 250 ml

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

TILMINJECT 300 mg/ml Solution for Injection for Cattle and Sheep.  
Tilmicosin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substance:**

Tilmicosin 300 mg

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

100 ml  
250 ml

**5. TARGET SPECIES**

Cattle and sheep.

**6. INDICATION(S)**

Read the package leaflet before use.

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

Subcutaneous use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period:

**Cattle:**

Meat and offal: 70 days

Milk: 36 days

**Sheeps:**

Meat and offal: 42 days

Milk: 18 days

If the product is administered to cows/sheeps during the dry period or to pregnant dairy heifers/ewes, milk should not be used for human consumption until 36/18 days after calving/lambing.

**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 broached use by .....

**11. SPECIAL STORAGE CONDITIONS**

Keep the vial in the outer carton in order to protect from light.

**12. SPECIAL 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.

For use by veterinary surgeons only.

**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 CALIER, S.A.

C/ Barcelonès, 26 (Pla del Ramassà)

LES FRANQUESES DEL VALLÈS, (Barcelona)

SPAIN

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

**17. MANUFACTURER’S BATCH NUMBER**

Batch{number}