

## **A. LABELLING**



**10. EXPIRY DATE**

EXP {month/year}  
Shelf life after first opening the container

**11. SPECIAL STORAGE CONDITIONS**

**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.

**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**

Alivira Animal Health Limited  
16 Glenoaks Close, Glenconner,  
Clonmel, Co Tipperary  
Ireland. E91T8Y6.

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

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Vials (100 ml/ 250 ml)**

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

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



**2. STATEMENT OF ACTIVE SUBSTANCES**

Tulathromycin                      100 mg/ml

**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: s.c.  
Pigs and sheep: i.m.

Read the package leaflet before use.

**8. 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.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Shelf life after first opening the container: 28 days.

Once broached use by

**11. SPECIAL STORAGE CONDITIONS**

**12. SPECIAL 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”**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Alivira Animal Health Limited  
16 Glenoaks Close, Glenconner,  
Clonmel, Co Tipperary  
Ireland. E91T8Y6.

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

**17. MANUFACTURER’S BATCH NUMBER**

Lot{number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Vial (50 ml)

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

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



**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Tulathromycin 100 mg/ml

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

50 ml

**4. ROUTE(S) OF ADMINISTRATION**

Cattle: s.c.  
Pigs and sheep: i.m.

**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.

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}  
Once broached use by

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.