

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{Paper box 50 ml, 100 ml}

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

TULATHROMYCIN Bioveta 100 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substance:**

Tulathromycin 100 mg

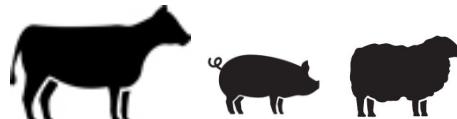
**3. PACKAGE SIZE**

50 ml

100 ml

**4. TARGET SPECIES**

Cattle, pigs, sheep.

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**Cattle: subcutaneous use.Pigs: intramuscular use.Sheep: intramuscular use.**7. WITHDRAWAL PERIODS**

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.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use by 28 days.

**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**

Bioveta, a.s.

**14. MARKETING AUTHORISATION NUMBERS****15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

{label 50 ml, 100 ml}

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

TULATHROMYCIN Bioveta 100 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

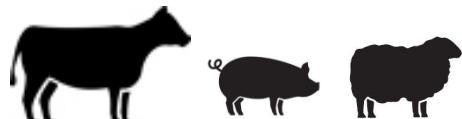
Each ml contains:

**Active substance:**

Tulathromycin 100 mg

**3. TARGET SPECIES**

Cattle, pigs, sheep.

**4. ROUTES OF ADMINISTRATION**Cattle: subcutaneous use.Pigs: intramuscular use.Sheep: intramuscular use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**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.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use by 28 days.

**7. SPECIAL STORAGE PRECAUTIONS**

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

Bioveta, a.s.



**9. BATCH NUMBER**

Lot {number}