

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

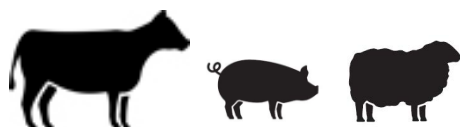
3. PACKAGE SIZE

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”
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Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
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For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
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Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a.s.



14. MARKETING AUTHORISATION NUMBERS
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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
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Bioveta, a.s.



9. BATCH NUMBER

Lot {number}