

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (20 ml / 50 ml / 100 ml / 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tulaven 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

20 ml
50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: subcutaneous use.
Pigs and sheep: intramuscular use.
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}

Once broached, use within 28 days.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/5018

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tulaven 100 mg/ml solution for injection for cattle
tulathromycin

2. STATEMENT OF ACTIVE SUBSTANCES

Tulathromycin: 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 22 days.
Not authorised for use in lactating cattle producing milk for human consumption.
Do not use in pregnant cows or heifers, 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 broached, use within 28 days.

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

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Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/5018

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (plastic - 100 ml / 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tulaven 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: SC
Pigs and sheep: IM
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}

Once broached, use within 28 days.

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

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Wooburn Green
High Wycombe
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HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/5018

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (plastic - 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tulaven 100 mg/ml solution for injection for cattle
tulathromycin

2. STATEMENT OF ACTIVE SUBSTANCES

Tulathromycin: 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 22 days.
Not authorised for use in lactating cattle producing milk for human consumption.
Do not use in pregnant cows or heifers, 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 broached, use within 28 days.

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

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Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/5018

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (20 ml - glass/ 50 ml - plastic)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tulaven 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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC
Pigs and sheep: IM

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:

7. EXPIRY DATE

EXP: {month/year}
Once broached, use within 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Tulaven 100 mg/ml solution for injection for cattle, pigs and sheep

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Tulathromycin: 100 mg

Excipients:

Monothioglycerol: 5 mg

Clear colourless to pale brownish yellow or slightly pink solution

4. INDICATION(S)

Cattle

Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* susceptible to tulathromycin. The presence of the disease in the group must be established before the product is used.

Treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis* susceptible to tulathromycin.

Pigs

Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Mycoplasma hyopneumoniae*, *Haemophilus parasuis* and *Bordetella bronchiseptica* susceptible to tulathromycin. The presence of the disease in the group must be established before the product is used. The veterinary medicinal product should only be used if pigs are expected to develop the disease within 2–3 days.

Sheep

Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent *Dichelobacter nodosus* requiring systemic treatment.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to macrolide antibiotics or to any of the excipients.

6. ADVERSE REACTIONS

Subcutaneous administration of the veterinary medicinal product to cattle causes very commonly transient pain reactions and local swellings at the injection site, that can persist for up to 30 days. No such reactions have been observed in pigs and sheep after intramuscular administration.

Pathomorphological injection site reactions (including reversible changes of congestion, oedema, fibrosis and haemorrhage) are very common for approximately 30 days after injection in cattle and pig.

In sheep transient signs of discomfort (head shaking, rubbing injection site, backing away) are very common after intramuscular injection. These signs resolve within a few minutes.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs and sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle

Subcutaneous use.

A single subcutaneous injection of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight). For treatment of cattle over 300 kg bodyweight, divide the dose so that no more than 7.5 ml are injected at one site.

Pigs

Intramuscular use.

A single intramuscular injection of 2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight) in the neck.

For treatment of pigs over 80 kg bodyweight, divide the dose so that no more than 2 ml are injected at one site.

Sheep

Intramuscular use.

A single intramuscular injection of 2.5 mg tulathromycin/kg body weight (equivalent to 1 ml/40 kg body weight) in the neck.

9. ADVICE ON CORRECT ADMINISTRATION

For any respiratory disease, it is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment within 48 hours after injection. If clinical signs of respiratory disease persist or increase, or if relapse occurs, treatment should be changed, using another antibiotic, and continued until clinical signs have resolved.

To ensure correct dosage bodyweight should be determined as accurately as possible to avoid underdosing. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper. The stopper may be safely punctured up to 20 times.

10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton or the vial after "EXP". The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Cross resistance occurs with other macrolides. Do not administer simultaneously with antimicrobials with a similar mode of action such as other macrolides or lincosamides.

Sheep:

The efficacy of antimicrobial treatment of foot rot might be reduced by other factors, such as wet environmental conditions, as well as inappropriate farm management. Treatment of foot rot should therefore be undertaken along with other flock management tools, for example providing dry environment.

Antibiotic treatment of benign foot rot is not considered appropriate. Tulathromycin showed limited efficacy in sheep with severe clinical signs or chronic foot rot, and should therefore only be given at an early stage of foot rot.

Special precautions for use in animals:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to tulathromycin and may decrease the effectiveness of treatment with other macrolides, lincosamides and group B streptogramins, due to the potential for cross resistance.

If a hypersensitivity reaction occurs, appropriate treatment should be administered without delay.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Tulathromycin is irritating to eyes. In case of accidental eye exposure, flush the eyes immediately with clean water.

Tulathromycin may cause sensitisation by skin contact resulting in e.g. reddening of the skin (erythema) and/or dermatitis. In case of accidental spillage onto skin, wash the skin immediately with soap and water.

Wash hands after use.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

If there is suspicion of a hypersensitivity reaction following accidental exposure (recognised by e.g. itching, difficulty in breathing, hives, swelling on the face, nausea, vomiting) appropriate treatment should be administered. Seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

In cattle at dosages of three, five or ten times the recommended dose, transient signs attributed to injection site discomfort were observed and included restlessness, head-shaking, pawing the ground, and brief decrease in feed intake. Mild myocardial degeneration has been observed in cattle receiving five to six times the recommended dose.

In young pigs weighing approximately 10 kg given three or five times the therapeutic dose transient signs attributed to injection site discomfort were observed and included excessive vocalisation and restlessness. Lameness was also observed when the hind leg was used as the injection site.

In lambs (approx. 6 weeks old), at dosages of three or five times the recommended dose, transient signs attributed to injection site discomfort were observed, and included walking backwards, head shaking, rubbing the injection site, lying down and getting up, bleating.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

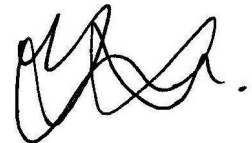
15. OTHER INFORMATION

Pack sizes

Cardboard box containing 1 glass vial of 20 ml
Cardboard box containing 1 plastic vial of 50 ml
Cardboard box containing 1 plastic vial of 100 ml
Cardboard box containing 1 plastic vial of 250 ml
Cardboard box containing 1 plastic vial of 500 ml

The 500 ml vials must not be used for pigs or sheep.

Not all pack sizes may be marketed.

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 19 October 2022