ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tulaxa 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 100 mg tulathromycin.

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs, sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Route of administration:
Cattle: s.c.
Pigs and sheep: i.m.

Dose:
1ml of product/40 kg body weight

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 opened use within 28 days

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package.
Once opened, store below 25°C.

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

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3073

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tulaxa 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains 100 mg tulathromycin.

3. TARGET SPECIES

Cattle, pigs, sheep.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

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

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 opened use within 28 days

7. SPECIAL STORAGE PRECAUTIONS

Store in the original package.
Once opened, store below 25°C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

1 ml contains:

Active substance:
Tulathromycin 100 mg

Excipients:
Monothioglycerol 5 mg

Clear, colourless to slightly yellow or slightly brown solution.

3. Target species

Cattle, pigs, sheep.

4. Indications for use

Cattle
Treatment and metaphylaxis of bovine respiratory disease 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 veterinary medicinal product is used.

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

Pigs
Treatment and metaphylaxis of swine respiratory disease 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 veterinary medicinal 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. Special warnings

Special warnings:
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 safe use in the target species:
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 veterinary medicinal product is used.
Use of the veterinary medicinal 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. 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.

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:
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.

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

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site reactions (congestion, oedema (swelling), fibrosis (scarring), haemorrhage, pain)[1]

[1]Reversible. May be observed or persist for approximately 30 days after injection.

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site reactions (congestion, oedema (swelling), fibrosis (scarring), haemorrhage)[1]

[1]Reversible, may be observed approximately for 30 days after injection.

Sheep:

Very common (>1 animal / 10 animals treated):	Discomfort (head shaking, rubbing injection site, backing away)[1]

[1]The signs resolve within a few minutes.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

Cattle
2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight).

A single subcutaneous injection. 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
2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight).

A single intramuscular injection 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
2.5 mg tulathromycin/kg bodyweight (equivalent to 1 ml/40 kg bodyweight).
A single intramuscular injection 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 a correct dosage, body weight should be determined as accurately as possible.

The cap may be safely punctured up to 20 times. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container.
Once opened, store below 25°C.
Shelf life after first opening the container: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the package after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/3073

Pack sizes:
A cardboard box with one bottle of 50 ml, 100 ml or 250 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
KRKA, d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Approved 18 May 2024

Gavin Hall