

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orojet® Lamb Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains:

Neomycin sulfate 70 mg. Streptomycin sulfate 70 mg.

Also contains sodium methyl parahydroxybenzoate 0.112% w/v, sodium ethyl parahydroxybenzoate 0.023% w/v and sodium propyl parahydroxybenzoate 0.016% w/v as antimicrobial preservative.

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

210 ml

5. TARGET SPECIES

Lambs.

6. INDICATION

Uses: (i) For prophylactic treatment in neonatal lambs as an aid to prevention of enteric infections including watery mouth.

(ii) For the treatment of neomycin and streptomycin sensitive enteric infections in neonatal lambs.

7. METHOD AND ROUTE OF ADMINISTRATION

Directions for use: To unlock the pump rotate in an anticlockwise direction. Depress plunger a sufficient number of times to prime the pump. Each depression of plunger then delivers approximately 1ml as a metered dose.

Dosage: For oral use only.

Lambs: Prophylaxis in neonates 1 ml per 5 kg bodyweight (1 metered dose) as soon as possible after birth i.e. within one hour.

Treatment: 1 ml per 5 kg bodyweight twice daily for three to four days.

Note: To avoid spillage when not in use, after administering the final dose, keep plunger depressed and turn in a clockwise direction to the 'closed' position.

SEE PACKAGE LEAFLET BEFORE USE.

8. WITHDRAWAL PERIOD

Lambs may be slaughtered for human consumption only after 28 days following last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Once opened, use within 14 days.

To be supplied only on veterinary prescription.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4093

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orojet® Lamb Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1.0 ml contains:

Neomycin sulfate 70 mg

Streptomycin sulfate 70 mg.

Also contains sodium methyl parahydroxybenzoate 0.112% w/v, sodium ethyl parahydroxybenzoate 0.023% w/v and sodium propyl parahydroxybenzoate 0.016% w/v as antimicrobial preservative.

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

210 ml

5. TARGET SPECIES

Lambs.

6. INDICATION

Uses:

(i) For prophylactic treatment in neonatal lambs as an aid to prevention of enteric infections including watery mouth.

(ii) For the treatment of neomycin and streptomycin sensitive enteric infections in neonatal lambs.

7. METHOD AND ROUTE OF ADMINISTRATION

Directions for use: To unlock the pump rotate in an anticlockwise direction. Depress plunger a sufficient number of times to prime the pump. Each depression of plunger then delivers approximately 1 ml as a metered dose.

Dosage: For oral use only.

Lambs: Prophylaxis in neonates: 1 ml per 5 kg bodyweight (1 metered dose) as soon as possible after birth, i.e. within one hour.

Treatment: 1 ml per 5 kg bodyweight twice daily for three to four days.

Note: To avoid spillage when not in use, after administering the final dose, keep plunger depressed and turn in a clockwise direction to the 'closed' position.

See package leaflet before use.

8. WITHDRAWAL PERIOD

Lambs must not be slaughtered for human consumption during treatment. Lambs may be slaughtered for human consumption only after 28 days following last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings:

Streptomycin may occasionally cause skin sensitisation in humans. Contact with skin should therefore be kept to a minimum. In case of accidental eye contact, wash eyes with copious amounts of water. Wash hands after use.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Once opened, use within 14 days.

Once opened, use by:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4093

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Orojet® Lamb Oral Solution

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Batch release site not listed

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orojet® Lamb Oral Solution

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Orojet Lamb is a brown oral solution. Each 1ml dose contains:

Neomycin sulfate	70 mg
Streptomycin sulfate	70 mg

Also contains sodium methyl parahydroxybenzoate 0.112% w/v, sodium ethyl parahydroxybenzoate 0.023% w/v and sodium propyl parahydroxybenzoate 0.016% w/v as antimicrobial preservative.

4. INDICATIONS

- (i) For prophylactic treatment in neonatal lambs as an aid to prevention of enteric infections including watery mouth.
- (ii) For the treatment of neomycin and streptomycin sensitive enteric infections in neonatal lambs.

5. CONTRAINDICATIONS

Not for use in known cases of hypersensitivity to neomycin and/or streptomycin.

6. ADVERSE REACTIONS

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7. TARGET SPECIES

Lambs.

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

For oral use only.

Lambs:

Prophylaxis in neonates: 1 ml per 5 kg bodyweight (1 metered dose) as soon as possible after birth i.e. within one hour.

Treatment:

1 ml per 5 kg bodyweight twice daily for three to four days. A metered 1 ml dose is achieved by means of the Orojet Lamb pump dispenser.

9. ADVICE ON CORRECT ADMINISTRATION

To unlock the pump, rotate in an anticlockwise direction. Depress the plunger a sufficient number of times to prime the pump.

To avoid spillage when not in use; after administering the final dose, keep plunger depressed and turn in a clockwise direction to the 'closed' position.

10. WITHDRAWAL PERIODS

Lambs must not be slaughtered for human consumption during treatment. Lambs may be slaughtered for human consumption only after 28 days following last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Once opened, use within 14 days.

When the container is broached for the first time, the date on which any product remaining in the container should be calculated. A statement of in-use shelf life of the product is given on this package insert. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNINGS

Avoid the introduction of contamination during use..

Operator Warnings

Streptomycin may occasionally cause skin sensitisation in humans. Contact with skin should therefore be kept to a minimum. In case of accidental eye contact, wash eyes with copious amounts of water. Wash hands after use.

For animal treatment only.

Keep out of the sight and reach of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Dispenser and plastic bottle containing 100 ml and 210 ml. Not all pack sizes may be marketed.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4093

Approved 04 September 2020

