SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orojet Lamb Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:	**per ml**
Neomycin Sulfate	70 mg
Streptomycin Sulfate	70 mg

Excipient(s):

Sodium methyl parahydroxybenzoate	0.112 % w/v
Sodium ethyl parahydroxybenzoate	0.023 % w/v
Sodium propyl parahydroxybenzoate	0.016 % w/v

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
A clear brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Lambs.

4.2 Indications for use, specifying the target species

i) For prophylatic treatment in neonatal lambs, as an aid to prevention of enteric infection including watery mouth.

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

4.3 Contraindications

Do not use in known cases of hypersensitivity to neomycin and / or streptomycin.

4.4 Special warnings

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Avoid the introduction of contamination during use.
For oral use only.

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

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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only.
Lambs: prophylaxis in neonates – 1 ml per 5kg bodyweight (1 metered dose from pump) 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The active ingredients are not significantly absorbed following oral administration.

4.11 Withdrawal period

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

5. PHARMACOLOGICAL PROPERTIES

Broad-spectrum bactericidal antibiotics. Antibacterial activity is mainly against aerobic, gram-negative bacteria. Both neomycin and streptomycin are poorly absorbed from the gastro-intestinal tract due to their low degree of liquid solubility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate
Sodium ethyl parahydroxybenzoate
Sodium propyl parahydroxybenzoate
Citric acid monohydrate
Sodium Citrate Dihydrate
Caramel Cerestar
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 14 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Translucent high-density polyethylene bottles of nominal capacity 112 ml and 250 ml, heat-sealed with black screw on plastic caps and a dispensing pump. The dispenser is pre-set to deliver approximately 1 ml per shot. Each bottle contains 100 ml, 210 ml or 240 ml of liquid. Each bottle is packed in an individual carton.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4093

9. DATE OF FIRST AUTHORISATION

26 July 1996

10. DATE OF REVISION OF THE TEXT

September 2020

Approved 04 September 2020