

CONSUMER PACKAGE INSERT FOR A VETERINARY MEDICINAL PRODUCT

The medicine is dispensed with a veterinarian's prescription only
For veterinary use only

1. NAME OF THE VETERINARY MEDICINE, DOSGE FORM AND STRENGHT:

Engemycin Spray Veterinary

Cutaneous spray

2. Active ingredients

Oxytetracycline hydrochloride 25.00 mg/ml

(equivalent to oxytetracycline 23.15 mg/ml)

Inactive ingredients

Patent blue V (E131) 1.25 mg/ml

A list of inactive ingredients is detailed in the section "Further Information".

3. WHAT IS THE MEDICINE INTENDED FOR:

For the treatment of the following infections caused by or associated with organisms sensitive to oxytetracycline in cattle, sheep and pigs:

- Foot infections caused in particular by: *Dichelobacter nodosus*, *Fusobacterium necrophorum*, and other *Fusobacterium* spp., and *Bacteroides* spp.
- Supporting treatment of superficial wound infections following surgery or physical injuries, e.g., tail biting in pigs, scratches and abrasions.

Therapeutic group: antibiotics for topical use, tetracyclines.

4. CONTRAINIDICATIONS:

Do not use for treatment of teats in order to prevent the veterinary medicinal product from getting into milk.

Do not use in animals in the cases of hypersensitivity to oxytetracycline or to any of the inactive ingredients.

5. SIDE EFFECTS

None.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

6. TARGET ANIMALS:

Cattle, sheep and pigs.

7. METHOD OF THE ADMINISTRATION AND DOSAGE:

A suspension in the form of a cutaneous spray.

For topical use only.

8. ADMINISTRATION OF THE MEDICINAL PRODUCT:

Shake well before use. The spray container is designed for use in either the upright or upside down position.

- The treated area must be well cleaned before being sprayed. Spray the product for 1–2 seconds at a distance of 15–20 cm until the area is of a uniform color. Repeat the treatment every 12 hours for 1–3 days depending on the healing process. To achieve the best results in case of pedal lesions it is advisable to follow the following instructions: fully clean the foot area, remove any foreign material, exudates and necrotic areas.
- keep the animal on dry ground for 12 hours following treatment .
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9. WITHDRAWAL PERIODS:

Cattle, sheep:

Meat: 0 days

Milk: 0 days

Pigs:

Meat: 0 days

Stained part of the pig skin must be removed prior to the rest of the animal being used for human consumption..

10. PRECAUTIONS:

- Special precautions for safe use in the target animal

The animals should be treated in a well ventilated area.

Do not spray in or near the eyes.

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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.

- Special safety precautions to be taken by the person handling the product

Because of the risk of sensitisation and contact dermatitis, the user should avoid skin contact. Wear appropriate impermeable gloves whilst handling the veterinary medicinal product.

Because of risk of eye irritation, contact with the eyes should be avoided. Protect the eyes and face.

Do not spray on a naked flame or any incandescent material.
Do not pierce or burn the container, even after use.
Avoid inhaling vapours.
Apply the veterinary medicinal product in the open air or in a well ventilated area.
Wash hands after use.
Do not eat or smoke whilst administering the veterinary medicinal product.
In case of accidental ingestion or in case of contact with eyes, seek medical advice immediately and show the package leaflet or the label to the physician..

- Pregnancy and lactation of the treated animal

Can be used during pregnancy and lactation

- Incompatibilities

Not known.

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a close place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/bottle.
- The expiry date refers to the last day of that month.
- Storage conditions
Store below 25°C.
Keep away from fire and sources of ignition – Do not smoke.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE PRODUCT/UNUSED PRODUCT AFTER USE:

Any unused veterinary product or waste materials derived from use of the veterinary product should be disposed of as toxic waste, do not throw to sewer

These measures should help to protect the environment
Ask the veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. FURTHER INFORMATION:

- In addition to the active(s) ingredient(s), the medicine also contains:

Isopropyl alcohol

Patent Blue V (E131)

Polysorbate 80

Mixture of hydrocarbons on butane basis (LPG), with denaturant

- What does the medicine look like and what is the content of the package:

A pressurized aluminum spray container containing 200 ml of product, 5 g oxytetracycline hydrochloride and a blue colorant. Green to green-blue suspension.

The spray valve allows use in the either an upright or upside down position.

- Package size:

A container holding 200 ml.

- **License holder name and address:**

Intervet Israel Ltd., Industrial Zone Neve-Ne'eman, Hod Hasharon 45240.

- **Manufacturer name and address:**

Intervet Productions SRL, Via Nettunense Km.20.300, Aprilla (LT) Italy.

Revised in June 2025.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

157-22-34471-00