The format of this leaflet was determined by the Ministry of Health and its content checked and approved in October 2016.

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 MEDICINE:

Engemycin Spray Veterinary

Cutaneous spray

2. COMPOSITION:

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* ssp., and *Bacteroides* spp.

Supporting treatment of superficial wound infections following surgery or physical injuries, e.g., tail biting in pigs, scratches and abrasions.

Pharmacotherapeutic group: antibiotics for topical use, tetracyclines.

4. CONTRAINIDICATIONS:

Do not spray on the udder of the treated animal in order to prevent traces of the active ingredient in the milk.

Do not use in the case 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. TARGET ANIMALS:

Cattle, sheep and pigs.

7. METHOD OF ADMINISTRATION AND DOSAGE:

A suspension in the form of a cutaneous spray.

For topical use only.

8. ADMINISTRATION OF 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 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.

For the best possible results in the case of foot lesions, it is advisable to adhere to the following instructions:

- Clean the foot area completely, remove any foreign material, exudates and necrotic areas.
- Keep the animals on dry ground for 12 hours following treatment.

9. WITHDRAWAL PERIODS:

Cattle, sheep:

Meat and offal: 0 days

Milk: 0 days

Pigs:

Meat and offal: 0 days

Remove any pigmented skin from the pig before the rest of the animal is used for human consumption.

10. PRECAUTIONS:

- Special precautions regarding use in the target animal

The animal should be treated in a well-ventilated area.

Do not spray into or near the eyes.

The use of this product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, treatment should be based on local epidemiological information regarding susceptibility of the target bacteria.

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

Because of the risk of sensitization and inflammation of the skin (dermatitis), the user should avoid skin contact. Wear impermeable gloves while handling the 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 vapors.

Apply the product in the open air or in a well-ventilated area.

Wash hands after use.

Do not eat or smoke while administering the product.

In case of accidental ingestion or in case of contact with eyes, seek medical advice and show the product leaflet/package to the physician.

- Pregnancy and lactation

Can be used in pregnant and lactating animals.

- Interaction with other medicines, and other forms of interaction

Not known.

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach 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 medical product or waste materials derived from such veterinary medicinal product use should be disposed of as toxic waste; do not discard into the wastewater.

13. FURTHER INFORMATION:

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

Patent Blue V (E131)

Polysorbate 80

Isopropyl alcohol

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 container containing 200 ml of product, 5 g oxytetracycline hydrochloride and a blue colorant.

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.

This leaflet was checked and approved by the Ministry of Health in October 2016**.**

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

157-22-34471-00