1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin Spray, 25 mg/ml, cutaneous spray, suspension for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

23,15 mg Oxytetracycline equivalent to 25,00 mg Oxytetracycline hydrochloride

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent blue V (E131)	1,25 mg
Polysorbate 80	
Isopropyl alcohol	
Mixture of hydrocarbons on butane basis (n-butane. isobutane, propane), with denaturant	

Green to green-blue suspension

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

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

Treatment of 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.

3.3 Contraindications

Do not use for treatment of teats in order to prevent the veterinary medicinal product from getting into milk.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The animals should be treated in a well ventilated area.
Do not spray in or near the eyes.

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 precautions to be taken by the person administering the veterinary medicinal product to animals:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep and pigs.

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For cutaneous use.

Shake well before use. The spray container is suitable to be used in upright and inverted positions. Before application properly clean the surface to be treated, spray the veterinary medicinal product for 1-2 seconds, at a distance of 15-20 cm, until the area has a homogeneous colour. Repeat the treatment every 12 hours for 1 to 3 days, depending on the healing process.

To achieve the best results in case of pedal lesions the following instructions are recommended:

- fully clean the foot area, completely removing foreign material, exudates and necrotic tissue
- keep the animal on dry ground for 12 hours after each application.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle, sheep:
Meat and offal: Zero days
Milk: Zero hours
Pigs:
Meat and offal: Zero days
Stained part of the pig skin must be removed prior to the rest of the animal being used for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QD06AA03

4.2 Pharmacodynamics

Oxytetracycline is produced by fermentation of *Streptomyces rimosus*.
It possesses broad spectrum antimicrobial activity against a wide range of Gram positive and Gram negative bacteria including target pathogens *Dichelobacter nodosus*, *Fusobacterium necrophorum* and other *Fusobacterium* spp., and *Bacteroides* spp.,
Oxytetracycline is bacteriostatic and acts by inhibiting protein synthesis within the cell.

4.3 Pharmacokinetics

When administered topically, oxytetracycline absorption is negligible and the drug comes into direct contact with bacteria on the skin and in superficial lesions on external body surfaces. The marker dye indicates the extent of the treated area.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C. Keep away from sources of ignition - No smoking.

5.4 Nature and composition of immediate packaging

Pressurised lacquered aluminium spray container containing in each 200 ml pack 5 g oxytetracycline hydrochloride and a blue colourant. The spraying valve consists of lacquered tinplate and different plastic materials and enables the container to be operated in upright and inverted positions.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/212/001

8. DATE OF FIRST AUTHORISATION

02 October 2009

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14 December 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).