ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Pressurised aluminium spray container containing 200 ml product

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin Spray, 25 mg/ml
Cutaneous spray suspension

2. COMPOSITION

Each ml contains:

Active substance:
23.15 mg Oxytetracycline equivalent to 25,00 mg Oxytetracycline hydrochloride

Excipients:
Patent blue V (E131) as colouring agent 1,25 mg

Green to green-blue suspension.

3. PACKAGE SIZE

200 ml.

4. TARGET SPECIES

Cattle, sheep and pigs.

5. INDICATIONS FOR USE

Indications for use

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.

6. CONTRAINDICATIONS

Contraindications

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 cases of hypersensitivity to oxytetracycline or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Major incompatibilities:

None known.

8. ADVERSE EVENTS

Adverse events

Cattle, sheep and pigs.

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

For topical use only.

Shake well before use. The spray container is suitable to be used in upright and inverted positions. Before application with the veterinary medicinal product 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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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.

11. WITHDRAWAL PERIODS

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.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the container after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/3028

Pack sizes

200 ml

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch releaseand contact details to report suspected adverse reactions:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Manufacturer for the batch release:
Intervet Productions S.r.l.
Via Nettunense, Km 20,300
04011 Aprilia (LT)
Italy

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

21. BATCH NUMBER

Lot {number}

Approved 18 May 2024

Gavin Hall