[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

ES: TENICOL, 25 mg/ml, suspensión para pulverización cutánea para bovino, ovino y porcino
FR: Engémycine S, 3.84% w/w, cutaneous spray, suspension for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains

Active substance:	
Oxytetracycline hydrochloride	25.00 mg
(equivalent to oxytetracycline	23.15 mg
Excipients:	
Patent blue V (E131)	1.25 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous spray, suspension
Green to green-blue suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use for treatment of teats in order to prevent the product from getting into milk.
Do not use in animals in cases of hypersensitivity to oxytetracycline or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

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

Use of the 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.

ii) 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 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 product in the open air or in a well ventilated area.
Wash hands after use.
Do not eat or smoke whilst administering the product.
In case of accidental ingestion or in case of contact with eyes, seek medical advice immediately and show the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical use only.

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 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.

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

None known.

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibiotics for topical use, tetracyclines
ATCvet code: QD06AA03

5.1 Pharmacodynamic properties

Oxytetracycline is produced by fermentation of *Streptomyces rimosus*.
It possesses broad spectrum antimicrobial activity against a wide range of Gram +ve and Gram -ve 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131)
Polysorbate 80
Isopropyl alcohol
Mixture of hydrocarbons on butane basis (n-butane. isobutane, propane), with denaturant

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4. 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.

6.5 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.

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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}>…

10 DATE OF REVISION OF THE TEXT

ANNEX III

LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

N.B. for the product there is no package leaflet. All information is directly on the container. Therefore the structure taken from the QRD8 template is the one foreseen for the leaflet

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(Pressurised aluminium spray container containing 200 ml product)

Engemycin Spray, 25 mg/mL, cutaneous spray, suspension for cattle, sheep and pigs
ES: TENICOL, 25 mg/ml, suspensión para pulverización cutánea para bovino, ovino y porcino
FR: Engémycine S, 3.84% w/w, cutaneous spray, suspension for cattle, sheep and pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
Represented in <country> by <national Intervet company>

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin Spray, 25 mg/mL
Cutaneous spray suspension for cattle, sheep and pigs

Oxytetracycline hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each mL contains:

Active substance:

Oxytetracycline hydrochloride	25.00 mg
(equivalent to oxytetracycline	23.15 mg

Excipients:

Patent blue V (E131) as colouring agent	1.25 mg

4. PHARMACEUTICAL FORM

Cutaneous spray, suspension
Green to green-blue suspension

5. INDICATIONS

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

Do not use for treatment of teats in order to prevent the product from getting into milk.
Do not use in animals in cases of hypersensitivity to oxytetracycline or to any of the excipients.

7. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned on this container, please inform your veterinary surgeon.

8. TARGET SPECIES

Cattle, sheep and pigs

9. DOSAGE FOR EACH SPECIES, ROUTE 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 properly clean the surface to be treated, spray the 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

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

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 after the expiry date stated on the container.

13. SPECIAL WARNING(S)

For topical use only.
The animals should be treated in a well ventilated area.
Do not spray in or near the eyes of the animals.
Use of the 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.
No negative effects due to the use of the product during pregnancy and lactation are known.

Because of the risk of sensitisation and contact dermatitis, the user should avoid skin contact. Wear appropriate impermeable gloves whilst 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 vapours.
Apply the product in the open air or in a well ventilated area.
Wash hands after use.
Do not eat or smoke whilst administering the product.
In case of accidental ingestion or in case of contact with eyes, seek medical advice immediately and show the label to the physician.

14. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

16. OTHER INFORMATION

Pack size is one container containing 200 ml.

17. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only - to be supplied only on veterinary prescription.

18. MARKETING AUTHORISATION NUMBER

19. MANUFACTURER’S BATCH NUMBER

<Batch> <Lot> <BN> {number}

20. EXPIRY DATE

EXP: end MM/YY