PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin LA 200 mg/ml, solution for injection
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains active substance Oxytetracyline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM

The recommended dosage rate is 20 mg/kg bodyweight (1 ml per 10 kg bodyweight) by deep intramuscular injection. The product is recommended for a single administration only. Maximum recommended dose at any one site:

Cattle: 20 ml

Pigs: 10 ml

Sheep: 5 ml

Piglets: 1 day 0.2 ml

7 days 0.3 ml

14 days 0.4 ml

21 days 0.5 ml

over 21 days 1.0 ml/10 kg

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods

Cattle: Meat and offal – 41 days
Milk – 8 days

Sheep: Meat and offal – 24 days
Milk – 7 days

Pigs: Meat and offal – 20 days

9. SPECIAL WARNING(S), IF NECESSARY

User warnings

Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur.

Take care to avoid accidental injection.

10. EXPIRY DATE

Lot / Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

Protect from light.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Keep the container in the outer carton.

When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

For Animal Treatment Only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder: MSD Animal Health UK Ltd., Walton Manor, Walton, Milton Keynes, MK7 7AJ

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24,
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4338

17. MANUFACTURER'S BATCH NUMBER

Lot / Expiry date:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABEL 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin LA 200 mg/ml, solution for injection
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains active substance Oxytetracycline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods
Cattle: Meat and offal – 41 days
Milk – 8 days
Sheep: Meat and offal – 24 days
Milk – 7 days
Pigs: Meat and offal – 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

10. EXPIRY DATE

Expiry end of:
Use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.
Following removal of the first dose use within 28 days. Discard unused contents.
Keep container in outer carton**.**

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

For Animal Treatment Only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder
MSD Animal Health UK Ltd., Walton Manor, Walton, Milton Keynes, MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4338

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50ML VIALS

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Engemycin LA 200 mg/ml solution for injection
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains active substance Oxytetracyline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

IM

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle: Meat and offal – 41 days; Milk – 8 days
Sheep: Meat and offal – 24 days; Milk – 7 days
Pigs: Meat and offal – 20 days.

6. BATCH NUMBER

B.N.:
DOM:

7. EXPIRY DATE

Expiry end of:
Use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

POM-V

To be supplied only on veterinary prescription

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder
MSD Animal Health UK Ltd., Walton Manor, Walton, Milton Keynes, MK7 7AJ

10. MARKETING AUTHORISATION NUMBER

Vm 01708/4338

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR: Engemycin LA 200 mg/ml, solution for injection

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Norbrook Laboratories
105 Armagh Road
Newry, Co Down
Northern Ireland, BT35 6PU

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin LA 200 mg/ml, solution for injection
Oxytetracycline

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

Each ml contains
Active substance
Oxytetracyline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)
Excipients
Sodium Formaldehyde Sulfoxylate 2 mg

A clear amber solution for injection.

4. INDICATION(S)

Engemycin LA is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity. Blood levels persist for at least 4 days. After administration by the intramuscular route maximum blood levels are achieved after 4 to 8 hours making Engemycin LA suitable for the treatment of acute

infections. Oxytetracycline has been shown to be effective *in vitro* against the following bacterial species:
Bordetella bronchiseptica, Trueperella pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Haemophilus somnus, Mannheimia haemolytica, Pasteurella multocida, Salmonella dublin, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes and *Streptococcus uberis*.

Engemycin LA is indicated for use in cattle, sheep and pigs in the treatment of: atrophic rhinitis caused by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida*; navel/joint ill caused by *Arcanobacterium pyogenes*, *E. coli* and *Staphylococcus aureus*; mastitis caused by *Arcanobacterium pyogenes*, *E. coli, Staphylococcus aureus, Streptococcus agalactiae* and *Streptococcus uberis*; metritis caused by *E. coli* and *Streptococcus pyogenes*; pasteurellosis and infections of the respiratory tract caused by *Mannheimia haemolytica* and *Pasteurella multocida*; septicaemia caused by *Salmonella dublin* and *Streptococcus pyogenes*; erysipelas caused by *Erysipelothrix rhusiopathiae.*

Engemycin LA can also be used in the control of enzootic abortion in sheep

5. CONTRAINDICATIONS

Do not use in horses, cats and dogs.

Do not use in animals suffering from renal or hepatic damage.

6. ADVERSE REACTIONS

Hypersensitivity, allergic or anaphylactic type reactions may occur in very rare cases based on post-marketing safety experience. In case of a serious anaphylactic reaction, the administration of appropriate treatment is recommended. Injection site reactions in cattle were observed very rarely based on post-marketing safety experience.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended dosage rate is 20 mg/kg bodyweight (1 ml per 10 kg bodyweight) administered by deep intramuscular injection. This product is recommended for a single administration only.

Maximum recommended dose at any one site:

Cattle		20 ml
Pigs		10 ml
Sheep		5 ml
Piglets	1 day	0.2 ml
	7 days	0.3 ml
	14 days	0.4 ml
	21 days	0.5 ml
	over 21 days	1 ml/10 kg

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD(S)

Cattle:	Meat and offal – 41 days
	Milk – 8 days
Sheep:	Meat and offal – 24 days
	Milk – 7 days
Pigs:	Meat and offal – 20 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Keep container in outer carton. Protect from light.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the container: 28 Days
When the container is broached for the first time, the date on which any product remaining in the container should be calculated using the in-use shelf-life. This discard date should be written in the space provided on the primary label.

When the vial has been broached and contents exposed to air, the solution may darken but the potency will be unchanged.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Do not dilute Engemycin LA 200 mg/ml.
If concurrent treatment is administered, use a separate injection site.
Resistance against oxytetracycline may vary.
Use of the product should be based on susceptibility testing of 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.
Inappropriate use of the product may increase the prevalence of bacteria resistant to oxytetracycline and may decrease the effectiveness of treatment with tetracyclines due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur.
Take care to avoid accidental injection.

Pregnancy and lactation:
The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration. The product can be safely administered to lactating animals.

Interaction with other medicinal products and other forms of interaction:
Oxytetracycline may interfere with the action of bactericidal antimicrobials such as penicillins and cephalosporins and should therefore not be used simultaneously.

Overdose (symptoms, emergency procedures, antidotes):
There is no known specific antidote, if signs of possible overdose occur, treat the animal symptomatically.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

Package Quantities: Multidose vials of 50 ml and 100 ml
Not all pack sizes may be marketed.

For Animal Treatment Only.

Legal category
POM-V To be supplied only on veterinary prescription.

Marketing authorisation number
Vm 01708/4338

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24,
Ireland.

Approved 24 August 2022