SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin LA 200 mg/ml, Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance
Oxytetracycline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

Excipient
Sodium Formaldehyde Sulfoxylate 2 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Clear amber solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs

4.2 Indications for use, specifying the target species

The product 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 *Trueperella pyogenes*, *Escherichia coli* or *Staphylococcus aureus*.
- Mastits caused by *Corynebacterium pyogenes*, *E. coli*, *Staphylococcus aureus, Streptococcus agalactiae* or *Streptococcus uberis*.
- Metritis caused by *E. coli* or *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*.

The product can also be used in the control of enzootic abortion in sheep.

4.3 Contra-indications

Do not use in horses, cats and dogs.
Do not use in animals suffering from renal or hepatic damage.

4.4 Special warning for each target species

None

4.5 Special precautions for use

(i) Special precautions for use in animals

Do not dilute the product.
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.

(ii) Special precautions to be taken by the person administering the medicinal product to the 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 plenty of water as irritation may occur.
Take care to avoid accidental injection.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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

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

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

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

There is no known specific antidote, if signs of possible overdose occur, treat the animal symptomatically.

4.11 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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATCvet Code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic that inhibits protein synthesis in susceptible bacteria. Inside the cell it binds irreversibly to receptors on the 30S subunit of the bacterial ribosome where it interferes with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis. The product is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity.

Oxytetracycline has a broad spectrum of activity, i.e. active against Gram-positive and Gram-negative organisms. Oxytetracycline has been shown to be effective in vitro against the following bacterial species: *Bordetella bronchiseptica, Corynebacterium pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Histophilus somni, Pasteurella haemolytica, Pasteurella multocida, Salmonella dublin, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes and Streptococcus uberis.*

5.2 Pharmacokinetic particulars

Blood levels persist for at least 4 days after administration by the intramuscular route. Maximum blood levels are achieved between 4 and 8 hours following intramuscular administration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium formaldehyde sulfoxylate
Magnesium Oxide Light
2-Pyrrolidone
Povidone K12
Monoethanolamine
Hydrochloric Acid
Water for Injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

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

Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C. Protect from light.

Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
When the vial has been broached and the contents exposed to air the solution may darken but the potency will be unchanged.

6.5 Nature and composition of immediate packaging

Amber type II glass vials of 50 ml and 100 ml sealed with Chlorobutyl Rubber Bungs and aluminium seal.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4338

9. DATE OF FIRST AUTHORISATION

20 February 1996

10. DATE OF REVISION OF TEXT

August 2022

Approved 24 August 2022