Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10 % DD Solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Oxytetracycline (as oxytetracycline hydrochloride)	100 mg

Excipients

Sodium formaldehyde sulphoxylate	5 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep, pigs, horses, dogs and cats.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by organisms sensitive to oxytetracycline in horses, cattle, sheep, pigs, dogs and cats.
In vitro, oxytetracycline is active against a range of both Gram-positive and Gram-negative microorganisms including: *Streptococcus* spp., *Staphylococcus* spp., *Listeria monocytogenes*, *Mannheimia haemolytica*, *Haemophilus parahaemolyticus* and *Bordetella bronchiseptica*, and against *Chlamydophila abortus*, the causative organism of enzootic abortion in sheep.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses during concomitant corticosteroid therapy.

4.4 Special warnings for each target species

Exercise caution when treating stressed horses with tetracyclines.

4.5 Special precautions for use

Special precaution(s) for use in 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Oxytetracycline is an irritant substance, especially in dogs and horses. Local reactions which may last up to 10 days have been observed following intramuscular administration in horses and subcutaneous administration in dogs.

In very rare cases, hypersensitivity (allergic) reactions to treatment may occur, which may require appropriate symptomatic treatment.

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

4.7 Use during pregnancy, lactation or lay

The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

DD = Dual dosage.
Engemycin 10% DD can be administered either every 24 hours at a low dose rate, or at a higher dose rate for prolonged duration of action.

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

24 hourly dosage regime:
Dose rate: 3 – 10 mg/kg body weight depending on age and species (see table).
Routes of administration: Intramuscular or intravenous injection in large animals. Subcutaneous or intramuscular injection in small animals.
The treatment may be repeated at 24 hour intervals up to 4 times (5 treatments in all).
Intravenous injections must be given slowly over a period of at least one minute.

Prolonged action dosage regime:
Dose rate: 10 or 20 mg/kg body weight depending on age and species (see table).
Route of administration: Intramuscular injection only, repeated once after 48 – 60 hours if required.
This dosage regime is not recommended for use in horses, dogs or cats.

Prophylactic treatment of enzootic abortion in sheep:
Dose rate: 20 mg/kg body weight administered between day 95 – 100 of gestation.
A further treatment may be given 2 – 3 weeks later.

Before administration, clean the area of the injection site and swab with spirit.
Repeat doses should be administered at different sites, and the sites massaged well after injection.
Maximum recommended dose at any one site: Adult cattle 20 ml, sheep and pigs 10 ml.

Animal	Body weight (kg)	24 hourly dose		Prolonged action dose	
		Dose (mg/kg)	Volume (ml)	Dose (mg/kg)	Volume (ml)
Horse	500	5	25	Not recommended	
Foal	100	10	10	Not recommended	
Cow	500	3	15	10	50
Calf	100	8	8	20	20
Sow/boar	150	5	7.5	10	15
Pig	25	8	2	20	5
Sheep	50	8	4	20	10
Lamb	25	8	2	20	5
Dog	10	10	1	Not recommended	
Cat	5	10	0.5	Not recommended	

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

Oxytetracycline has a low toxicity, but is an irritant substance. Overdose should be avoided, particularly in horses.

4.11 Withdrawal Period(s)

24 hourly dosage regime:
Meat and offal:
Cattle: IM use: 35 days; IV use: 9 days.
Sheep: IM use: 35 days; IV use: 9 days.
Pigs: IM use: 13 days; IV use: 9 days.
Horses: 6 months.

Milk: Cattle and sheep: 96 hours.

Prolonged action dosage regime:
Meat and offal:
Cattle: 21 days.
Sheep: 18 days.
Pigs: 10 days.

Milk: The prolonged action dosage regime is not authorised for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracyclines
ATCvet Code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic which has broad spectrum antibacterial activity against both Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

After absorption it enters most tissues and body fluids, with the exception of CSF.
It is excreted unchanged, mainly in urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium formaldehyde sulphoxylate
Magnesium oxide
Povidone K12
Ethanolamine
Water for injections

6.2 Incompatibilities

Dilution with calcium salts is not recommended as this may lead to precipitation of crystals.

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 °C. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Multidose vials of 100 ml. Amber glass Type II (Ph.Eur.) or PET vials closed with a halogenated butyl rubber stopper with aluminium overseal.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/071/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988.
Date of last renewal: 30 September 2008.

10 DATE OF REVISION OF THE TEXT

November 2016