SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10% DD solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance per ml:
Oxytetracycline (as hydrochloride) 100 mg

Antioxidant preservative per ml:
Sodium formaldehyde sulphoxylate 5 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Clear, yellow, aqueous solution for injection

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, **c**attle, sheep and pigs

In vitro, oxytetracycline is active against a range of both Gram-positive and Gram-negative micro organisms including:
Streptococcus spp., Staphylococcus spp., *L. monocytogenes*, *P. haemolytica, H. parahaemolyticus* and *B. bronchiseptica* and against *Chlamydophila abortus*, the causative organism of enzootic abortion in sheep

4.3 Contra-indications

Not to be administered to horses during concomitant therapy with corticosteroids.

4.4 Special warning for each target species

As with other tetracyclines, caution should be exercised in treating horses under stress.
Exercise caution in animals with hepatic or renal impairment.

4.5 Special precautions for use

i. Special precautions for use in animals

Not for intravenous administration in dogs or cats.

ii. Special precautions to be taken by the person administering the medicinal product to the animals

Take care to avoid accidental injection.
In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

A transient swelling may be observed following intramuscular administration in horses and subcutaneous administration in dogs.
Photodermatitis may occur after treatment if exposure to intense sunlight occurs.

4.7 Use during pregnancy and lactation

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

It is not recommended to administer bacteriostatic and bactericidal antibiotics concurrently.

4.9 Amounts to be administered and administration route

Can be administered at either a low dose rate for a 24 hour duration of activity or at a high dose rate for prolonged duration of activity.

24 hour dosage regime:
The recommended dosage rate is 3-10 mg/kg bodyweight (depending on age and species - see table) by intramuscular or intravenous injection in large animals and by 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:
10 or 20 mg/kg bodyweight depending on age and species (see table) by intramuscular injection only, repeated once after 48-60 hours if required.
This dosage regime is not advised for use in horses, dogs or cats.

Animal	Weight kg	24 hour dosage		Prolonged action	
		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	

Prophylactic treatment of enzootic abortion in sheep: 20 mg/kg administered about 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: 20 ml for cattle, 10 ml for sheep and pigs.

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

Oxytetracyline has low toxicity, but is irritant. Overdosage should be avoided, particularly in horses. No recommended treatment.

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

24 hour dose

Milk Cows	6 days
Cattle	35 days
Sheep	14 days
Pigs	14 days

Prolonged action dose

Milk Cows	6 days
Cattle	21 days
Sheep	14 days
Pigs	10 days

Not for use in horses intended for human consumption.
Not for use in sheep producing milk for human consumption.

Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Oxytetracycline is a bacteriostatic antibiotic which has broad spectrum antibacterial activity against both gram-positive and gram-negative bacteria. After absorption it enters most tissues and body fluids, with the exception of CSF. It is excreted unchanged, mainly in urine.

ATC Vet code: QJ01AA06

5.2 Pharmacokinetics properties

From the site of injection the drug is effectively and rapidly absorbed with minimal irritation of the tissue thanks to the low viscosity of the solvent contained in the formulation, polyvinyl pyrrolidone (PVP).
Depending on the dose rate the duration of the action after a single administration is for 24 hours or prolonged to 48 – 60 hours.
After a standard dose of 3-8 mg oxytetracycline/kg BW to target animals, drug peak plasma concentrations were achieved in 1 - 4 hours and lasted to the level of 0.5 - 1.0 µg/mL, regarded as effective, in about 24 hours; by giving IM doses of 10 – 20 mg oxytetracycline/kg BW the action was prolonged and concentrations exceeding 0.5 – 1.0 µg/ml were maintained for about 48 hours.
The drug is widely distributed in the body with highest concentrations in liver, spleen, kidneys and the lungs. Oxytetracycline is moderately protein bound (about 50 %) and is excreted mainly unchanged by renal route, with same in the faeces and milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium formaldehyde sulphoxylate
Magnesium Oxide
Povidone K12
Ethonolamine
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time

Shelf life: 2 years
Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C. Protect from light. Do not freeze.
Keep container in outer carton.

6.5 Nature and composition of immediate packaging

Vials of amber Type II (Ph Eur) glass or PET closed with halogenated butyl rubber stopper with aluminium overseal.
Multi-dose vials of 100 ml.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4136

9. DATE OF FIRST AUTHORISATION

11 December 1995

10. DATE OF REVISION OF TEXT

January 2025

Gavin Hall
Approved: 08 January 2025