

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin DD 100 mg/ml Solution for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Oxytetracycline (as hydrochloride) 100 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium formaldehyde sulfoxylate	5 mg
Magnesium oxide	
Povidone K12	
Ethanolamine	
Water for injections	

A clear yellow aqueous solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

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

### 3.2 Indications for use for each 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.

### 3.3 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.

### 3.4 Special warnings

Exercise caution when treating stressed horses with tetracyclines.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

People with known hypersensitivity to oxytetracycline should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Sheep, pigs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction <sup>1</sup>
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<sup>1</sup> A veterinarian should be consulted immediately and appropriate treatment should be initiated.

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction <sup>1</sup> , Anaphylaxis <sup>1</sup>
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<sup>1</sup> A veterinarian should be consulted immediately and appropriate treatment should be initiated.

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis <sup>1</sup> , Injection site reaction <sup>2</sup>

<sup>1</sup> A veterinarian should be consulted immediately and appropriate treatment should be initiated..

<sup>2</sup> Following intramuscular administration, may last up to 10 days. Oxytetracycline is an irritant substance.

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction <sup>1</sup> , Injection site reaction <sup>2</sup>
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<sup>1</sup> A veterinarian should be consulted immediately and appropriate treatment should be initiated.

<sup>2</sup> Following subcutaneous administration, may last up to 10 days. Oxytetracycline is an irritant substance.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy:

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

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

DD = Dual dosage.

The veterinary medicinal product 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	

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

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

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.**

Not applicable.

### **3.12 Withdrawal periods**

#### **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.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QJ01AA06

### **4.2 Pharmacodynamics**

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

### **4.3 Pharmacokinetics**

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

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

### **5.2 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.

### **5.3 Special precautions for storage**

Do not store above 25°C. Protect from light. Do not freeze.

### **5.4 Nature and composition of immediate packaging**

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

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Intervet Ireland Ltd.

## **7. MARKETING AUTHORISATION NUMBER(S)**

VPA10996/071/001

## **8. DATE OF FIRST AUTHORISATION**

01/10/1988

## **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

24/04/2024

## **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).