SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10% Farm Pack 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 injection	

An aqueous clear, green to yellow solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, pigs and horses.

3.2 Indications for use for each target species

For the treatment of infections caused by organisms sensitive to oxytetracycline in horses, cattle, 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*, *M. haemolytica, H. parahaemolyticus* and *B. bronchiseptica* and against *Chlamydophila abortus*, the causative organism of enzootic abortion in sheep.

3.3 Contraindications

Do not administer to horses during concomitant therapy with corticosteroids.
Do not use in cases of hypersensitivity to oxytetracycline or tetracycline antibiotics.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
As with other tetracyclines, caution should be exercised in treating horses under stress.

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

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[1], Anaphylaxis[1]

[1] A veterinarian should be consulted immediately and appropriate treatment should be initiated.

Horses:

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

[1] A veterinarian should be consulted immediately and appropriate treatment should be initiated.
[2] Following intramuscular administration, transient.
Pigs and sheep:
None known.

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 its local representative or the national

competent authority via the national reporting system. See 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 tooth discolouration.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

The veterinary medicinal product 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:
Intramuscular use or intravenous use.
The recommended dosage is 3-10 mg/kg bodyweight (depending on age and species - see table) by intramuscular or intravenous injection. The treatment may be repeated at 24 hour intervals up to 4 times (5 treatments in total).
Intravenous injections must be given slowly over a period of at least one minute.

Prolonged action dosage regime:
Intramuscular use.
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.

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

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.

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

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

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

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

<u>24 hour dose</u>
Milk:

Cattle	6 days

Meat and offal:

Cattle	35 days
Sheep	14 days
Pigs	14 days

<u>Prolonged action dose</u>
Milk:

Cattle	6 days

Meat and offal:

Cattle	21 days
Sheep	14 days
Pigs	10 days

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

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

4.3 Pharmacokinetics

From the site of injection, the drug is effectively and rapidly absorbed with minimal irritation of the tissue due to the low viscosity of the solvent contained in the formulation, polyvinyl pyrrolidone (PVP).
Depending on the dose rate the duration of 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 bodyweight 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 intramuscular doses of 10 – 20 mg oxytetracycline/kg bodyweight 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 the renal route, with same in the faeces and milk.

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.
Do not freeze.
Protect from light.
Keep the container in the outer carton.

5.4 Nature and composition of immediate packaging

Multidose amber type II glass vials closed with a light grey or red-brown halogenated butyl rubber stopper with an aluminium overseal.
Multidose amber PET vials closed with a light grey halogenated butyl rubber stopper with an aluminium overseal.

Pack size:
Cardboard box containing 1 x 250 ml vial.

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

Medicines should not be disposed of via wastewater.

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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4135

8. DATE OF FIRST AUTHORISATION

27 August 1998

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

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 27 April 2026