MSD Animal Health UK Limited

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Engemycin® 10% DD Solution for injection

Species: Cats, Cattle, Dogs, Horses and other equidae, Pigs, Sheep

Therapeutic indication:Pharmaceuticals: Antimicrobials: Injections

Active ingredient: Oxytetracycline Hydrochloride

Product: Engemycin® 10% DD Solution for injection

Product index: Engemycin® 10% DD

Cattle - milk:144 hours

Cattle - meat:35 days

Sheep - meat:14 days

Pig - meat:14 days

Incorporating:

Qualitative and quantitative composition

Qualitative and quantitative composition:

Each ml contains:

Active substance:

Oxytetracycline (as hydrochloride) 100 mg

Excipients:

Sodium formaldehyde sulfoxylate 5 mg

For the full list of excipients, see section “Pharmaceutical particulars”.

Pharmaceutical form

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

Clinical particulars

Target Species

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

Indications for use

For the treatment of infections caused by organisms sensitive to oxytetracycline in cattle, sheep, pigs, horses, dogs and cats.

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.

Contraindications

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

Special warnings for each target species

None.

Special precautions for use

As with other tetracyclines, caution should be exercised in treating horses under stress.

Exercise caution in animals with hepatic or renal impairment.

Not for intravenous administration in dogs or cats.

Operator warnings

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.

Adverse Reactions

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reacti

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

2 May occur if exposure to intense sunlight occurs after treatment.

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Very rare (<1 animal / 10,000 animals reports):
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis1; Injection site swelling2; Photosensiti

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

2 Following intramuscular administration, transient.

3 May occur if exposure to intense sunlight occurs after treatment.

Sheep, pigs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

1 May occur if exposure to intense sunlight occurs after treatment.

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection s

1 Following intramuscular administration, transient.

2 May occur if exposure to intense sunlight occurs after treatment.

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.

Use during pregnancy or lactation

Pregnancy:

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

Interactions

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

Amounts to be administered and administration route

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:

NOAH Compendium

Large animals: Intramuscular use or intravenous use.

Small animals: Subcutaneous use or intramuscular use.

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 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, dogs or cats.

Animal	**Weight kg**	**24 hour dosage**		**Prolong**
		Dose mg/kg	Volume ml	Dose m
Horse	500	5	25	Not rec
Foal	100	10	10	Not rec
Cow	500	3	15	10
Calf	100	8	8	20
Sow/boar	150	5	7.5	10
Pig	25	8	2	20
Sheep	50	8	4	20
Lamb	25	8	2	20
Dog	10	10	1	Not rec
Cat	5	10	0.5	Not rec

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.

Overdose

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

Withdrawal periods

24 hour dose

Milk:	6 days
Cattle	
Meat and offal:	35 day
Cattle	
Sheep	14 day
Pigs	14 day

Prolonged action dose

Milk:	6 days
Cattle	
Meat and offal:	21 day
Cattle	
Sheep	14 day
Pigs	10 day

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.

Pharmacological particulars

ATCvet code: QJ01AA06.

Pharmacotherapeutic group

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.

Pharmacokinetic properties

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.

Pharmaceutical particulars

Excipients

Sodium formaldehyde sulfoxylate

Magnesium oxide

Povidone K12

Ethanolamine

Water for injection

Major incompatibilities

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

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.

Special precautions for storage

Do not store above 25 °C.

Do not freeze.

Protect from light.

Keep the container in the outer carton.

Immediate packaging

Vials of amber type II glass or PET closed with halogenated butyl rubber stopper with an aluminium overseal.

Pack size:

Cardboard box containing a multi-dose vial of 100 ml.

Disposal

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.

Marketing Authorisation Holder (if different from distributor)

Intervet International B.V., represented by MSD Animal Health UK Limited.

Marketing Authorisation Number

UK: Vm 06376/4136

Significant changes

Date of the first authorisation or date of renewal

11 December 2005

Date of revision of the text

September 2025.

Any other information

For animal treatment only. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description: Engemycin 10% DD 1x100ml:

GTIN:8713184011251