

FOR ANIMAL USE ONLY

ENGEMYCIN® 10%

Injectable Solution

Reg. No. G2470 (Act 36/1947)

Namibia Reg. No. V98/17.1.2/668 NS0

Engemycin® 10% is an aqueous oxytetracycline injectable solution for the treatment and control of disease conditions caused by or associated with oxytetracycline susceptible organisms.

INDICATIONS

Cattle: For the treatment of tick-borne gallsickness (anaplasmosis), heartwater, bacterial pneumonia, mastitis, bacterial enteritis, navel/joint-ill and bacterial wound infections.

Horses: For the treatment of strangles, bacterial pneumonia and enteritis.

Pigs: For the treatment of bacterial pneumonia, mastitis, bacterial enteritis, navel/joint-ill and bacterial wound infections.

Sheep and Goats: For the treatment of heartwater, bacterial pneumonia, footrot, mastitis, navel/joint-ill and bacterial wound infections.

COMPOSITION

Engemycin® 10% is an aqueous solution containing oxytetracycline in a complex with magnesium oxide and polyvinylpyrrolidone.

CONTENTS

Each 1 ml of **Engemycin® 10%** contains 100 mg oxytetracycline in a complex with magnesium oxide and polyvinylpyrrolidone in water for injection. It contains sodium formaldehyde-desulfoxylate as a preservative.

STORAGE

- Store in the dark, below 25 °C.
- Do not freeze.
- Protect from exposure to direct sunlight.

WARNINGS

- **Withdrawal periods**
Meat and other organs : 14 days after the last dosage.
Milk : 60 hours after the last dosage.
- The use of tetracyclines during the period of tooth development including late pregnancy may lead to tooth discolouration.
- A darkened solution must be discarded.
- *Rapid intravenous injection may result in an acute shock reaction and collapse.*
- Discard empty vials and disposable needles and syringes in accordance with local waste disposal regulations.
- **KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.**
- Although this remedy has been tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- Do not administer to animals known to be allergic to oxytetracyclines (infrequent allergies may occur).
- Do not inject piglets with iron preparations on the same day.
- Do not dilute with calcium salts as this may lead to precipitation of crystals which would make the solution not suitable for intravenous infusion.
- Oxytetracycline must be used with caution in animals with existing kidney impairment.

- Consult a veterinarian for an accurate diagnosis.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

- For the control of bacterial infections, 3 to 5 doses are required.
- For the indication of anaplasmosis/heartwater, the recommended dose is 20 mg/kg intravenously (i.v.) or intramuscularly (i.m.).
- Repeat intramuscular or subcutaneous (s.c.) injections should be given at different sites.
- Not more than 20 ml should be given at any 1 site.
- Intravenous injections should be given slowly over a period of at least 1 minute.
- Observe aseptic conditions when administering the injection.

DOSAGE

Cattle and Horses

- Intramuscular injections of 1 ml/10 kg body mass (10 mg/kg) i.v./i.m. should be made deep into the fleshy part of the muscle. Administer in a minimum of 2 locations to limit the volume per site.

Pigs

- 1 ml/10 kg body mass (10 mg/kg) s.c. or i.m.
- In very young pigs below 10 kg body mass, the subcutaneous route is preferred.
- Pigs in excess of 10 kg body mass, administer by intramuscular injection at 1 site in the neck.
- In pigs weighing over 100 kg the dose should be divided and administered at 2 injection sites.
- Do not administer more than 0,5 ml oxytetracycline in piglets of less than 2 kg body mass.

Sheep and Goats

- 1 ml/10 kg body mass (10 mg/kg) i.v./i.m.
- In sheep and goats over 50 kg body mass, the dose should be divided and administered at 2 injection sites.

PRESENTATION

100 ml and 500 ml amber bottles or PET flasks each packed in a cardboard box.

REGISTRATION HOLDER

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MANUFACTURER

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SLEGS VIR DIEREGBRUIK

ENGEMYCIN® 10%

Inspuitbare Oplossing

Reg. Nr. G2470 (Wet 36/1947)

Namibië Reg. Nr. V98/17.1.2/668

NS0

Zimbabwe Reg. Nr. E94/80.22.10.9381

Engemycin® 10% is 'n waterige oksitetrasiklien inspuitbare oplossing vir die behandeling en beheer van siektetoestande veroorsaak deur of geassosieer met oksitetrasikliensensitiewe organismes.

INDIKASIES

Beeste: Vir die behandeling van bosluisoorgedraagde galsiekte (anaplasrose), hartwater, longontsteking, mastitis, bakteriële enteritis, naelstringsiekte, gewrigsontsteking en bakteriële wondinfeksies.

Perde: Vir die behandeling van nuwesiekte, longontsteking en enteritis.

Varke: Vir die behandeling van longontsteking, mastitis, bakteriële enteritis, naelstringsiekte, gewrigsontsteking en bakteriële wondinfeksies.

Skape en Bokke: Vir die behandeling van hartwater, longontsteking, vrotpootjie, mastitis, naelstringsiekte, gewrigsontsteking en bakteriële wondinfeksies.

BERGING

- Berg in die donker, benede 25 °C.
- Moenie vries nie.
- Beskerm teen direkte sonlig.

SAMESTELLING

Engemycin® 10% is 'n waterige oplossing wat oksitetrasiklien in 'n kompleks met magnesiumoksied en polivinielpirollidoon bevat.

INHOUD

Elke 1 ml Engemycin® 10% bevat 100 mg oksitetrasiklien in 'n kompleks met magnesiumoksied en polivinielpirollidoon in water vir inspuiting. Dit bevat natriumformaldehyd-desulfoksilaat as 'n preserveermiddel.

WAARSKUWINGS

Onttrekkingsperiode

Vleis en ander organe: 14 dae na die laaste dosering.

Melk: 60 ure na die laaste dosering.

- Die gebruik van tetrasikliene gedurende tandontwikkeling, insluitende laat dragtigheid, mag tandverkleuring tot gevolg hê.
- 'n Verdonkerde oplossing moet weggegooi word.
- *Vinnige binnearse inspuiting mag akute skok en ineenstorting veroorsaak.*
- HOU BUIITE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
- Alhoewel hierdie middel breedvoerig onder 'n wye verskeidenheid toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer.

VOORSORGMATREËLS

- Moenie aan diere wat allergies is vir oksitetrasiklien toedien nie (ongereelde allergieë mag voorkom).
- Moenie varkies op dieselfde dag met ysterpreparate inspuit nie.
- Moenie met kalsiumsoute verdun nie, aangesien dit tot die presipitasie van kristalle mag aanleiding gee, wat die oplossing ongeskik vir binnearse infusie sal maak.
- Oksitetrasiklien moet versigtig gebruik word by diere met nierversaking.
- Raadpleeg 'n veearts vir akkurate diagnose.

GEBRUIKSAANWYSINGS

GEBRUIK SLEGS SOOS AANGEDUI.

- Drie tot vyf dosisse word benodig om bakteriële infeksie te beheer.
- Herhaalde binnespiers of onderhuidse (o.h.) inspuiting moet op verskillende inspuitingsplekke toegedien word. Nie meer as 20 ml mag op 1 plek toegedien word nie.
- Binnearse inspuiting moet stadig oor ten minste 1 minuut toegedien word.
- Vir anaplasrose/hartwater is die aanbevole dosis 20 mg/kg intraveneus (i.v./intramuskulêr (i.m.)
- *Aseptiese voorsorgmaatreëls moet nagekom word wanneer die inspuitings toegedien word.*

Dosis

Beeste en Perde

1 ml per 10 kg liggaamsmassa (10mg/kg) i.v./i.m. Binnespiers inspuitings moet diep in die vleisagtige deel van die spier toegedien word. Inspuitings moet ten minste in 2 areas toegedien word om die volume per area te beperk.

Varke

1 ml per 10 kg liggaamsmassa (10 mg/kg) o.h./i.m.

By jong varkies onder 10 kg liggaamsmassa word die onderhuidse roete aanbeveel.

By varke met 'n liggaamsmassa van meer as 10 kg word daar binnespiers by 1 plek op die nek ingespuut.

By varke met 'n liggaamsmassa van meer as 'n 100 kg liggaamsmassa word dit aanbeveel dat die dosis verdeel word en op 2 plekke ingespuut word.

Daar moet nie meer as 0,5 ml oksitetrasiklien by varkies met 'n liggaamsmassa van minder as 2 kg liggaamsmassa toegedien word nie.

Skape en Bokke

1 ml/10 kg liggaamsmassa (10 mg/kg) i.v./i.m..

By skape/bokke van meer as 50 kg liggaamsmassa moet die dosis gedeel word en op 2 inspuutingsplekke toegedien word.

AANBIEDING

100 ml en 500 ml in bruin glasbottels of PET flessies elk verpak in kartonhouers.

VERVAARDIGER

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