

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10% Farm Pack, Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

OXYTETRACYCLINE, (as Hydrochloride Ph. Eur.) 100 mg/ml

Also contains antioxidant sodium formaldehyde sulphonylate.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES









Aqueous solution for injection for the treatment of horses, cattle, sheep, pigs.

6. INDICATION(S)

Aqueous solution for injection for the treatment of horses, cattle, sheep, pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M. + I.V.

 500 kg 24 h. 25 ml	 100 kg 24h. 10 ml	 500 kg 24h. 15 ml PA-50 ml	 100 kg 24h. 8 ml PA-20 ml
 150 kg 24 h. 7.5 ml PA-15 ml	 25 kg 24h. 2 ml PA-5 ml	 25 kg 24h. 2 ml PA-5 ml	 50 kg 24h. 4 ml PA-10 ml

Maximum dose volume at any one site: cattle 20 ml, pigs and sheep 10 ml

8. WITHDRAWAL PERIOD

24 hour dose

Milk Cows: 6 days

Meat Cattle: 35 days

Sheep: 14 days

Pigs: 14 days

Prolonged action dose

Milk Cows: 6 days

Meat 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information and warnings before use.

10. EXPIRY DATE

Expiry end of:

11. SPECIAL STORAGE CONDITIONS

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

Do not freeze. Following removal of the first dose use within 28 days.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

[Distribution category]

To be supplied only on veterinary prescription.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4374

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10% Farm Pack, Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

OXYTETRACYCLINE, (as Hydrochloride) 100 mg/ml

Also contains antioxidant sodium formaldehyde sulphonylate.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Aqueous solution for injection for the treatment of horses, cattle, sheep and pigs.

6. INDICATION(S)

Aqueous solution for injection for the treatment of horses, cattle, sheep and pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M. + I.V.

Maximum dose volume at any one site: cattle 20 ml; pigs and sheep 10 ml.

8. WITHDRAWAL PERIOD

24 hour dose

Milk Cows: 6 days

Meat Cattle: 35 days

Sheep: 14 days

Pigs: 14 days

Prolonged action dose

Milk Cows:	6 days
Meat 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information and warnings before use.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze. Protect from light. Keep the container in the outer carton. Following removal of the first dose, use within 28 days.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet for further information and warnings before use.

Following removal of the first dose use within 28 days.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Limited
Milton Keynes, Bucks.MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4374

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR:

Engemycin 10% Farm Pack Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder:

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturers responsible for batch release:

Intervet International GmbH	Intervet Productions s.r.l.
Feldstrasse 1 a	Via Nettunense Km.20,300
85716 Unterschleissheim	I-04011 Aprilia (LT)
Germany	Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10% Farm Pack, Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A clear, yellow aqueous solution for injection containing 100 mg per ml of oxytetracycline (as the hydrochloride). Antioxidant sodium formaldehyde sulphoxylate.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

- Do not administer to horses during concomitant therapy with corticosteroids.
- A transient swelling may be observed following intramuscular administration in horses.
- The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.

6. ADVERSE REACTIONS

7. TARGET SPECIES

The treatment of infections caused by organisms sensitive to oxytetracycline in horses, cattle, sheep and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Engemycin 10% Farm Pack 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.

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.

ANIMAL	24 HOUR DOSAGE			PROLONGED ACTION DOSAGE	
	WEIGHT KG	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. Maximum recommended dose at any one site: cattle 20 ml, pigs and sheep 10 ml. Repeat doses should be administered at different sites, and the sites massaged well after injection.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

24 hour dose

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

Prolonged action dose

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

Not to be used in sheep producing milk for human consumption.

Not to be used 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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Do not freeze. Keep container in outer carton. Following withdrawal of the first dose use the product within 28 days. When the product is broached for the first time, calculate the discard date and write this in the space provided on the label. (A statement of the in-use shelf life of the product is given on the packaging insert, from which the discard date may be calculated). Dilution with calcium salts is not recommended as this may lead to precipitation of crystals.

12. SPECIAL WARNING(S)

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2021

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

Vm 01708/4374

PACKAGE QUANTITIES

Glass bottles or polyethylene terephthalate (PET) bottles containing 250 ml.

Further information

Engemycin 10% Farm Pack has been specifically formulated to reduce pain on injection without the need for addition of a local anaesthetic. As with other tetracyclines, caution should be exercised in treating horses under stress.

Distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 08 December 2021

