PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10% DD*, solution for injection

*Dual Dosage

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

OXYTETRACYCLINE, (as Hydrochloride) 100 mg/ml

Antioxidant sodium formaldehyde sulphoxylate.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

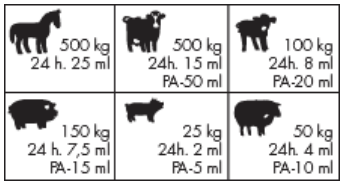
Aqueous solution for injection for the treatment of horses, cattle, sheep, pigs, dogs and cats.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M. + I.V. + S.C.



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

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. Discard unused contents.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4136

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Engemycin 10% DD*, solution for injection

*Dual Dosage

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

Antioxidant sodium formaldehyde sulphoxylate.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

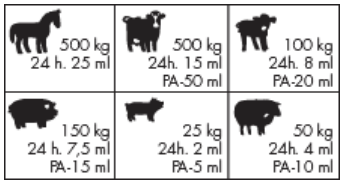
Aqueous solution for injection for the treatment of horses, cattle, sheep and pigs.

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. + S.C.



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

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

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information and warnings before use.

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

10. EXPIRY DATE

Expiry:

Once broached use by:

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. Discard unused contents. Keep container in outer carton.

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:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Distributed in Northern Ireland by:
Intervet Ireland Ltd, Magna Drive,
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4136

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR:

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

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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% DD, solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHERINGREDIENTS

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 bacteria 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, *L. monocytogenes*, *M. haemolytica*,
H. parahaemolyticus and *B. bronchiseptica*, and against *Chlamydophila abortus,* the causative organism of enzootic abortion in sheep. Oxytetracycline is bacteriostatic.

5. CONTRAINDICATIONS

- Do not use in sheep producing milk for human consumption.
- Do not administer to horses during concomitant therapy with corticosteroïds.
- A transient swelling may be observed following intramuscular administration in horses and subcutaneous administration in dogs.
- 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 bacteria sensitive to oxytetracycline in horses,cattle, sheep, pigs, dogs and cats.

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

DD = Dual dosage. Engemycin® 10% DD can be administered at either a low dose rate for 24 hour duration of activity or at 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 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:

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.

	24 hour dosage			Prolonged action dosage	
Animal	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
Dog	10	10	1	Not recommended	
Cat	5	10	0.5	Not recommended	

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: 20 ml cattle, 10 ml sheep and pigs. 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.
Following withdrawal of the first dose use the product within 28 days. When container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

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 PRODUCTOR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority**.** Dilution with calcium salts is not recommended as this may lead to precipitation of crystals. Keep container in outer carton.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.
Vm 06376/4136
UK authorised veterinary medicinal product.
PACKAGE QUANTITIES
Glass bottles or polyethylene terephthalate (PET) bottles containing 100 ml.
Further information
Engemycin® 10% 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 and animals with renal or hepatic impairment.

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

Gavin Hall

Approved: 08 January 2025