ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml provides tiamulin base equivalent to 200 mg tiamulin hydrogen fumarate in sesame oil.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

For the treatment of (i) swine dysentery caused by *Brachyspira hyodysenteriae* and complicated by
Fusobacterium spp. and *Bacteroides* spp., (ii) arthritis caused by *Mycoplasma hyosynoviae* to reduce lameness and restore growth performance, and (iii) enzootic pneumonia complex caused by *Mycoplasma hyopneumoniae* and where the secondary bacteria are sensitive to tiamulin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION
Swine Dysentery treatment
The dose is 1ml/20 kg bodyweight (equivalent to 10 mg tiamulin hydrogen fumarate/kg bodyweight) administered intramuscularly as a single treatment to pigs showing clinical signs of the disease.

Mycoplasmal Arthritis Treatment and Enzootic Pneumonia Complex in Pigs
The dose is 1.5 ml/20 kg bodyweight (equivalent to 15 mg tiamulin hydrogen fumarate/kg bodyweight) administered intramuscularly for a period of 3 consecutive days to pigs showing clinical signs of the disease.
The maximum volume to be administered at any one intramuscular injection site should not exceed 10 ml.

Swab the septum before removing each dose.
Use a dry sterile needle and syringe.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods
Meat and offal: 22 days

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings
For user warnings see package leaflet.

Contra-indications
Animals should not receive products containing monensin, narasin or salinomycin during or for at least seven days before or after treatment with Denagard 200 mg/ml Solution for Injection. Severe growth depression or death may result.

PRECAUTIONS
For intramuscular use in pigs only.
On rare occasions, erythema or mild oedema of the skin may occur in pigs following the use of this product.
As the product is formulated with sesame oil, it is important to ensure that the syringe used is dry. The admixture of oil and water may cause the plunger to stick.

10. EXPIRY DATE

Expiry date {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate.
This product does not contain an antimicrobial preservative.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material

12. SPECIAL 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. To be supplied only on veterinary prescription.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
D-27472 Cuxhaven
Groden
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 52127/5080

17. MANUFACTURER'S BATCH NUMBER

Batch No {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON (10x100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml provides tiamulin base equivalent to 200 mg tiamulin hydrogen fumarate in sesame oil.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

10 x 100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Swine Dysentery, Enzootic Pneumonia Complex of Pigs, Mycoplasmal Arthritis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Swine Dysentery Treatment
Administer as a single intramuscular injection at 1 ml/20 kg bodyweight (equivalent to 10 mg tiamulin
hydrogen fumarate/kg bodyweight).

Mycoplasmal Arthritis Treatment and Enzootic Pneumonia Complex in Pigs
The dose is 1.5 ml/20 kg bodyweight (equivalent to 15 mg tiamulin hydrogen fumarate/kg bodyweight) administered intramuscularly for a period of 3 consecutive days to pigs showing clinical signs of the disease.
For intramuscular injection only.
The maximum volume to be administered at any one intramuscular injection site should not exceed 10 ml.

Swab the septum before removing each dose.
Use a dry sterile needle and syringe

8. WITHDRAWAL PERIOD(S)

WITHDRAWAL PERIODS
Meat and offal: 22 days

9. SPECIAL WARNING(S), IF NECESSARY

Animals should not receive products containing monensin, narasin or salinomycin during or for at least seven days before or after treatment with Denagard 200 mg/ml Solution for Injection.
Severe growth depression or death may result.
For full dosage information and all contra-indications, see package leaflet.

USER WARNINGS
For user warnings see package leaflet.
To be used as directed by a veterinary surgeon.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate.
This product does not contain an antimicrobial preservative. Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
Keep the container in the outer carton.

12. SPECIAL 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. To be supplied only on veterinary prescription.

POM-V

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
D-27472 Cuxhaven
Groden
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 52127/5080

17. MANUFACTURER'S BATCH NUMBER

LOT {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (Concertina Label)

100ml VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml provides tiamulin base equivalent to 200 mg tiamulin hydrogen fumarate in sesame oil.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Swine Dysentery, Enzootic Pneumonia Complex of Pigs, Mycoplasmal Arthritis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Swine Dysentery Treatment
Administer as a single intramuscular injection at 1 ml/20 kg bodyweight (equivalent to 10 mg tiamulin hydrogen fumarate/kg bodyweight).

Mycoplasmal Arthritis Treatment and Enzootic Pneumonia Complex in Pigs
The dose is 1.5 ml/20 kg bodyweight (equivalent to 15 mg tiamulin hydrogen fumarate/kg bodyweight) administered intramuscularly for a period of 3 consecutive days to pigs showing clinical signs of the disease.

For intramuscular injection only.
The maximum volume to be administered at any one intramuscular injection site should not exceed 10 ml.

8. WITHDRAWAL PERIOD(S)

Meat and Offal: 22 days

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS, WARNINGS, ETC.

Animals should not receive products containing monensin, narasin or salinomycin during or for at least seven days before or after treatment with Denagard 200 mg/ml Solution for Injection.
Severe growth depression or death may result. For full dosage information and all contra-indications, see package leaflet.

USER WARNINGS
For user warnings see package leaflet.
To be used as directed by a veterinary surgeon.
Swab the septum before removing each dose.
Use a dry sterile needle and syringe.

10. EXPIRY DATE

EXP {month/year}

Date to discard:____/____/

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Do not store above 25°C.
Do not refrigerate.
This product does not contain an antimicrobial preservative. Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

12. SPECIAL 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. To be supplied only on veterinary prescription.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
D-27472 Cuxhaven
Groden
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 52127/5080

17. MANUFACTURER'S BATCH NUMBER

LOT {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Denagard 200 mg/ml Solution for Injection

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

Marketing authorisation holder:
Elanco GmbH
Heinz-Lohmann Strasse 4
D-27472 Cuxhaven
Groden
Germany

Manufacturer responsible for batch release:
Elanco France S.A.S.
26 Rue de la Chapelle
F-68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 200 mg/ml Solution for Injection

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

Denagard 200 mg/ml Solution for Injection is in the form of a clear, pale yellow, sterile, oily solution for intramuscular administration to pigs.
Each ml provides tiamulin base, equivalent to 200 mg tiamulin hydrogen fumarate, formulated in sesame oil.

4. INDICATION(S)

ACTIONS
The following organisms show sensitivity to tiamulin in vitro:
Brachyspira
Brachyspira hyodysenteriae, Brachyspira pilosicoli.
Mycoplasmas
Mycoplasma hyopneumoniae, M. hyorhinis, M.hyosynoviae, Ureaplasma spp.
Gram-positive
Staphylococcus spp*., Streptococcus* spp*., Corynebacterium pyogenes.*
Gram-negative
Pasteurella spp*., Klebsiella pneumoniae, Actinobacillus (Haemophilus)* spp*., Fusobacterium necrophorum, Bacteroides* spp*., Campylobacter coli, Lawsonia intracellularis.*

INDICATIONS
For the treatment of swine dysentery caused by *Brachyspira hyodysenteriae* complicated by *Fusobacterium* spp. and *Bacteroides* spp.

For the treatment of enzootic pneumonia complex caused by *M. hyopneumoniae* and where the secondary bacteria are sensitive to tiamulin.
For the treatment of arthritis caused by *Mycoplasma hyosynoviae* to reduce lameness and restore growth performance.

5. CONTRAINDICATIONS

Contra-indications
Animals should not receive products containing monensin, narasin or salinomycin, during or for at least seven days before or after treatment with Denagard 200 mg/ml Solution for Injection.
Severe growth depression or death may result.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Pigs

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

Swine Dysentery Treatment
The dose is 1 ml/20 kg bodyweight (equivalent to 10 mg tiamulin hydrogen fumarate/kg bodyweight) administered intramuscularly as a single treatment to pigs showing clinical signs of the disease. Follow up treatment should be provided when necessary either with Denagard 12.5% Oral Solution in the drinking water or Denagard Premix in the feed.

Mycoplasmal Arthritis Treatment and Enzootic Pneumonia Complex of Pigs Treatment
The dose is 1.5 ml/20 kg bodyweight (equivalent to 15 mg tiamulin hydrogen fumarate/kg bodyweight) daily, administered intramuscularly for a period of 3 consecutive days to pigs showing clinical signs of the disease.
The maximum volume to be administered at any one intramuscular injection site should not exceed 10 ml.

9. ADVICE ON CORRECT ADMINISTRATION

Swab the septum before removing each dose.
Use a dry sterile needle and syringe.

10. WITHDRAWAL PERIOD(S)

Withdrawal Periods
Meat and offal: 22 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Do not refrigerate.
This product does not contain an antimicrobial preservative.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

12. SPECIAL WARNING(S)

Precautions
For intramuscular use in pigs only.
On rare occasions, erythema or mild oedema of the skin may occur in pigs following the use of this product.
As the product is formulated with sesame oil, it is important to ensure that the syringe used is dry.
The admixture of oil and water may cause the plunger to stick.

User Warnings
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.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
In case of skin contact with the product, wash immediately with running water in order to minimise absorption through the skin.
In case of eye contact with the product, wash immediately with running water and seek medical advice.

FOR ANIMAL TREATMENT ONLY.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

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

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

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

PRESENTATION: 100 ml multidose glass vials.

To be supplied only on veterinary prescription.

POM-V

Vm 52127/5080

Approved 29 April 2025
Gavin Hall