

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1L bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 12.5% w/v Concentrate for Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Tiamulin hydrogen fumarate solution.

Presentation: An aqueous solution containing 125 mg tiamulin hydrogen fumarate per ml. The solution also contains methylparahydroxybenzoate (0.9 mg/ml) and propylparahydroxybenzoate (0.1 mg/ml) as preservatives.

3. PHARMACEUTICAL FORM

Concentrate for Oral Solution

4. PACKAGE SIZE

1 Litre

5. TARGET SPECIES

For oral administration in the drinking water of pigs, chickens and turkeys.

6. INDICATION(S)

USES: The following organisms show sensitivity to tiamulin hydrogen fumarate *in vitro*:

Brachyspira: *Brachyspira hyodysenteriae*, *B. pilosicoli*.

Mycoplasmas: *Mycoplasma hyopneumoniae*, *M. hyorhinis*, *M. hyosynoviae*, *Ureaplasma spp.*, *M. gallisepticum*, *M. synoviae*, *M. meleagridis*.

Gram-positive: *Staphylococcus spp.*, *Streptococcus spp.*, *Arcanobacterium pyogenes*.

Gram-negative: *Pasteurella spp.*, *Klebsiella pneumoniae*, *Actinobacillus (Haemophilus) spp.*,

Fusobacterium necrophorum, *Bacteroides spp.*, *Campylobacter coli*, *Lawsonia intracellularis*.

INDICATIONS

Pigs: For the treatment, prevention and control of swine dysentery caused by *Brachyspira hyodysenteriae* and complicated by *Fusobacterium* and *Bacteroides* spp.

Chickens: For the reduction in the severity of disease caused by mycoplasmas.

Turkeys: For the reduction in the severity of disease caused by mycoplasmas.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

Pigs: The dosage of Denagard 12.5% Oral Solution is 8.8 mg of the active substance per kg bodyweight daily (equivalent to 10 ml of the product per 142 kg bodyweight) administered in the drinking water of pigs for 3–5 days depending on the severity of the infection and/or the duration of the disease. The contents of each 1 litre bottle will treat 188 pigs of 25 kg bodyweight for three days or 114 pigs of 25 kg bodyweight for 5 days. To ensure an intake of 8.8 mg/kg daily, Denagard 12.5% Oral Solution may be administered in one of two ways.

- Denagard 12.5% Oral Solution may be administered in approximately one half of the daily water requirements to ensure consumption of the correct dose.

Unmedicated water should be provided each day after the medicated water has been consumed. The dosage rate, calculated on a liveweight basis, is equivalent to 10 ml per 142 kg bodyweight.

- Denagard 12.5% Oral Solution may be administered continuously at a level of 60 ppm of active substance in the drinking water as the only source of drinking water. The daily requirement should be added to the drinking water at the rate of 9.6 ml solution per 20 litres (4.5 gallons) of water.

Where a water medicator is used, the appropriate stock solution should be made up according to the makers instructions.

Chickens: The dosage for chickens is 25 mg of active substance per kg bodyweight (equivalent to 100 ml of product per 500 kg bodyweight).

Tiamulin should be administered at 0.025% in drinking water (2 ml product per litre water) for 3–5 days and will provide approximately the following daily dosage of tiamulin depending on the age of the bird:

Day old chick:	125–150 mg/kg bodyweight
4 week old broiler:	30–50 mg/kg bodyweight
10 week old pullet:	30–45 mg/kg bodyweight
Layer:	25 mg/kg bodyweight

Turkeys: The dosage for turkeys is 25 mg of active substance per kg bodyweight (equivalent to 100 ml of product per 500 kg bodyweight).

Tiamulin should be administered at 0.025% tiamulin in the drinking water (2 ml product per litre water) for 5 days and will provide approximately the following daily dosage of tiamulin depending on the age of the bird:

1 week old poul:	70 mg/kg bodyweight
4 week old poul:	50 mg/kg bodyweight
8 week old poul:	25–30 mg/kg bodyweight
20 week old poul:	25 mg/kg bodyweight

Fresh solutions of tiamulin-medicated drinking water should be made up each day.

8. WITHDRAWAL PERIOD(S)

Withdrawal Periods: Animals and birds must not be slaughtered for human consumption during treatment. Pigs may be slaughtered for human consumption only after 2 days from the last treatment. Chickens may be slaughtered for human consumption only after 2 days from the last treatment. Eggs – zero days. Turkeys

may be slaughtered for human consumption only after 5 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications: Do not use in animals hypersensitive to the active ingredient. Animals and birds should not receive products containing monensin, narasin or salinomycin, during or for at least seven days before or after treatment with Denagard 12.5% Oral Solution. Severe growth depression or death may result. Concomitant use of tiamulin and the ionophore anticoccidial maduramicin may lead to a mild to moderate growth depression in chickens. The situation is transient and recovery normally occurs within 3–5 days following withdrawal of tiamulin treatment. This does not seem to occur with the ionophores lasalocid or semduramicin.

In order to avoid interactions between tiamulin and the incompatible ionophores monensin, narasin and salinomycin, the feed mill supplying the feed should be notified that tiamulin will be used and that these products should not be included in the feed or contaminate the feed.

The feed should be tested for the ionophores prior to use if there is any suspicion that contamination of the feed might occur.

If an interaction does occur, stop tiamulin water medication immediately and replace with fresh water. Remove contaminated feed as soon as possible and replace with feed not containing the tiamulin-incompatible ionophores.

Operator Warnings: When mixing, direct contact with the skin and eyes should be avoided by wearing impermeable rubber gloves and safety glasses. In case of accidental eye contact, irrigate the eyes thoroughly with clean running water immediately.

Seek medical advice if irritation persists.

Contaminated clothing should be removed and any splashes on to the skin should be washed off immediately.

Wash hands after use.

Pregnancy and Lactation: Denagard 12.5% Oral Solution is suitable for use during pregnancy and lactation. Tiamulin may be used in laying and breeding birds as it has been shown to have no adverse effects on egg production, fertility and hatchability in chickens and turkeys.

PRECAUTIONS

- For use in drinking water of pigs, chickens and turkeys only.
- Monitor water intake at frequent intervals during medication.
- If there is no response to treatment within five days, the diagnosis should be re-established.
- On rare occasions, erythema or mild oedema of the skin may occur in pigs following the use of tiamulin hydrogen fumarate.
- Water intake may be depressed during the administration of tiamulin to birds. It appears to be concentration dependent with 0.025% tiamulin reducing intake by approximately 15%. It does not appear to have any adverse effect on overall performance of the birds or efficacy of the product.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Pharmaceutical Warnings: Do not store above 25°C. Fresh medicated water must be prepared every 24 hours. Watering equipment should be thoroughly cleaned prior to addition of Denagard 12.5% Oral Solution.

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

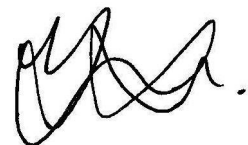
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4052

17. MANUFACTURER’S BATCH NUMBER

Lot {number}



Approved: 22 October 2020