SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 12.5% w/v Concentrate for Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance		
Tiamulin hydrogen fumarate	125.0 mg/ml	12.5% w/v
Excipients		
Antimicrobial preservatives		
Methyl parahydroxybenzoate	0.9 mg/ml	0.09% w/v
Propyl parahydroxybenzoate	0.1 mg/ml	0.01% w/v

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for oral solution.
Pale yellow aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs, chickens and turkeys

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

Animals and birds should not receive products containing monensin, narasin or salinomycin, during or for at least seven days before or after treatment. Severe growth depression or death may result.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

Not applicable.

ii) Special precautions for the person administering the veterinary medicinal product to animals

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.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

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 dependant 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.

4.7 Use during pregnancy, lactation or lay

The product can be used in pregnant and lactating pigs.
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.

4.8 Interaction with other medicinal products and other forms of interaction

Animals and birds should not receive products containing monensin, narasin or salinomycin during or for at least seven days before or after treatment. 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.

4.9 Amounts to be administered and administration route

Pigs:
The dosage is 8.8 mg of the active substance per kg bodyweight daily, (equivalent to 10 ml solution per 142 kg bodyweight) administered in the drinking water of pigs for 3 to 5 days, depending on the severity of the infection and/or the duration of the disease.
The contents of each 250 ml bottle will treat 46 pigs of 25 kg bodyweight for 3 days or 28 pigs of 25 kg bodyweight for 5 days.
The contents of each 1 litre bottle will treat 188 pigs of 25 kg bodyweight for 3 days or 114 pigs of 25 kg bodyweight for 5 days.

To ensure an intake of 8.8 mg/kg daily, the product may be administered in one of two ways:

i) Administer 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 solution per 142 kg bodyweight.
ii) Administer 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 always be made up according to the maker's instructions.
If there is no response to treatment within 5 days, the diagnosis should be re-established.

Chickens:
The dosage for chickens is 25 mg of active substance per kg bodyweight (equivalent to 100 ml solution per 500 kg bodyweight). Tiamulin should be administered at 0.025% in drinking water (2 ml product per litre of 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 solution per 500 kg bodyweight). Tiamulin should be administered at 0.025% in drinking water (2 ml product per litre of water) for 5 days and will provide approximately the following daily dosage of tiamulin depending on the age of the bird.

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

Monitor water intake at frequent intervals during medication.
Fresh solutions of tiamulin-medicated drinking water should be made up each day.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

There is a relatively high therapeutic index with tiamulin and the likelihood of an overdosage is considered remote, especially as water intake and hence tiamulin intake is reduced if abnormally high concentrations are given. The LD5 for chickens is 1290 mg/kg bodyweight and for turkeys 840 mg/kg bodyweight.

The clinical signs of toxicity in chickens are: vocalization, clonic cramps and lying in a lateral position. Symptoms in turkeys are: clonic cramps, lateral or dorsal position, salivation and ptosis.

If signs of intoxication do occur, promptly remove the medicated water and replace with fresh water.

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-infective for systemic use
ATCVet Code: QJ01XQ01

5.1 Pharmacodynamic properties

Tiamulin hydrogen fumarate is a semi-synthetic diterpene antibiotic. The mode of action is by inhibition of ribosomal protein synthesis in sensitive bacteria. It is a bacteriostatic antibiotic and the following organisms show sensitivity *in vitro:*

Brachyspira: *Brachyspira hyodysenteriae, B. pilosicoli*
Mycoplasmas: *Mycoplasma hyopneumoniae, M. hyorhinis, M. hyosynoviae,* Ureaplasma spp*., M. gallisepticum, M. synoviae, and 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*.

5.2 Pharmacokinetic properties

Following oral administration, tiamulin hydrogen fumarate is rapidly absorbed and peak serum concentrations are achieved 2 - 4 hours after administration and concentrates in some tissues e.g. lung. Following administration, it is rapidly metabolised and excreted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Citric acid monohydrate
Sodium phosphate dihydrate
Ethanol 96%
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25°C.
Fresh medicated water must be prepared every 24 hours.

6.5 Nature and composition of immediate packaging

250 ml high density polyethylene bottle with screw cap.
1 litre high density polyethylene bottle with screw cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/5066

9. DATE OF FIRST AUTHORISATION

31 July 1992

10. DATE OF REVISION OF THE TEXT

December 2025

Gavin Hall
Approved: 23 December 2025