

[Version 8.1,01/2017]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tialin 125 mg/ml concentrate for oral solution for pigs, chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml concentrate contains:

Active substance:

Tiamulin hydrogen fumarate 125.0 mg, corresponding to 101.2 mg tiamulin

Excipients:

Methyl parahydroxybenzoate 0.9 mg

Propyl parahydroxybenzoate 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for oral solution.

Clear, colourless to pale yellow 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

Special precautions for use in animals

Not applicable.

Special precautions to be taken by 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.

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 or 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 or 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 to 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 body weight daily, (equivalent to 10 ml solution per 142 kg body weight) 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 1 litre bottle will treat 188 pigs of 25 kg body weight for 3 days or 114 pigs of 25 kg body weight 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 live weight basis, is equivalent to 10 ml solution per 142 kg body weight.
- 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 body weight (equivalent to 100 ml solution per 500 kg body weight). Tiamulin should be administered at 0.025% in drinking water (2 ml product per litre of water) for 3 to 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 body weight
4 week old broiler:	30 – 50 mg/kg body weight
10 week old pullet:	30 – 45 mg/kg body weight
Layer:	25 mg/kg body weight

Turkeys:

The dosage for turkeys is 25 mg of active substance per kg body weight (equivalent to 100 ml solution per 500 kg body weight). 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 poults:	70 mg/kg body weight
4 week old poults:	50 mg/kg body weight
8 week old poults:	20 – 30 mg/kg body weight
20 week old poults:	25 mg/kg body weight

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 overdose is considered remote, especially as water intake and hence tiamulin intake is reduced if abnormally high concentrations are given. The LD₅₀ for chickens is 1290 mg/kg body weight and for turkeys 840 mg/kg body weight.

The clinical signs of toxicity in chickens are: vocalisation, 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

Meat and offal:

Pigs:	2 days
Chickens:	2 days
Turkeys:	5 days

Eggs:
Chickens: zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-infective for systemic use.
ATC vet 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. hyorhinalis*, *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 particulars

Following oral administration, tiamulin hydrogen fumarate is rapidly absorbed and peak serum concentrations are achieved 2 to 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
Disodium phosphate dihydrate
Ethanol 96%
Water purified

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 3 months.

Shelf life after dilution or reconstitution according to directions: 24 hours.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

- HDPE container of 1000 ml with LDPE closure.
- HDPE container of 5000 ml with HDPE closure.

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

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

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE