

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tiamutin 12.5% Aqueous Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Tiamulin hydrogen fumarate 125.0 mg

Excipients

Methyl parahydroxybenzoate 0.9 mg

Propyl parahydroxybenzoate 0.1 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

Yellowish, viscous aqueous solution with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Target Species

Porcine.

4.2 Indications for use, specifying the target species

For the oral treatment of swine dysentery caused by *Serpulina (Treponema) hyodysenteriae* complicated by *Fusobacterium* spp. and *Bacteroides* spp.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

Animals should not receive products containing monensin, salinomycin or narasin during or for at least seven days before or after treatment with Tiamutin 12.5% Solution. Severe growth depression or death may result.

4.4 Special warnings for each target species

For use in the drinking water of pigs only.

4.5 Special precautions for use

Special precaution(s) for use in animals

Fresh medicated water must be prepared every 24 hours.

If there is no response to treatment within five days, the diagnosis should be re-established. Severely affected pigs that do not drink should be medicated with Tiamutin 200 Injection.

Watering equipment should be inspected and cleaned prior to addition of Tiamutin 12.5% solution.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

When mixing, direct contact with the skin should be avoided. Any splashes on the skin should be washed off immediately.

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.

4.7 Use during pregnancy, lactation or lay

Tiamutin is suitable for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Animals should not receive products containing monensin, salinomycin or narasin during or for at least seven days before or after treatment with Tiamutin 12.5% Solution. Severe growth depression or death may result.

4.9 Amounts to be administered and administration route

For the treatment of clinical swine dysentery

The dose is 8.8 mg tiamulin hydrogen fumarate per kg bodyweight per day, equivalent to 10 ml Tiamutin 12.5% Solution per 142 kg bodyweight. To be administered in the drinking water for 3 to 5 days depending on the severity or duration of the disease.

To ensure an intake of 8.8 mg per kg bodyweight per day of active substance, Tiamutin 12.5% Solution may be administered in one of two ways:

1) The daily requirement 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.

Or

2) Tiamutin 12.5% Solution may be administered continuously at a level of 60 ppm of active substance, tiamulin hydrogen fumarate, in the drinking water.

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

Tiamulin hydrogen fumarate is well tolerated at dose levels well above those employed therapeutically.

4.11 Withdrawal Period(s)

Pigs may be slaughtered for human consumption only after 48 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterial for systemic use.
ATCvet Code: QJ01XQ01.

5.1 Pharmacodynamic properties

Action

The following organisms show *in vitro* sensitivity to tiamulin:

- | | |
|---------------|---|
| Serpulina | - <i>S. (Treponema) hyodysenteriae</i> |
| Mycoplasma | - <i>M. hyopneumoniae</i> (syn <i>M. suipneumoniae</i>)
<i>M. hyorhinis</i> , <i>M. hyosynoviae</i> , <i>M. gallisepticum</i> ,
<i>M. synoviae</i> , <i>M. meleagridis</i> , <i>M. dispar</i> ,
<i>M. bovis</i> , <i>M. bovirhinis</i> , <i>Ureaplasma spp.</i> |
| Leptospira | - <i>Leptospira spp.</i> |
| Gram-Positive | - <i>Staphylococcus spp.</i> , <i>Streptococcus spp.</i>
<i>Actinomyces (Corynebacterium) pyogenes</i> . |
| Gram-Negative | - <i>Klebsiella pneumoniae</i> , <i>Actinobacillus</i> ,
<i>Haemophilus spp.</i> , <i>Fusobacterium</i>
<i>necrophorum</i> , <i>Campylobacter coli</i> , <i>Bacteroides spp.</i> ,
<i>Pasteurella spp.</i> |

5.2 Pharmacokinetic properties

Tiamutin is well absorbed from the gastrointestinal tract of pigs and appears in the blood within 30 minutes, the peak concentrations occurring approximately 2 hours after the oral administration of a single dose of 10 mg/kg. An average of 85% of a single dose is absorbed, 98% of that absorbed is excreted in the urine and faeces within 72 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Citric Acid Monohydrate
Disodium Phosphate Dihydrate
Ethanol
Purified Water

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

Store below 25° C.

6.5 Nature and composition of immediate packaging

250 ml, 1 litre and 4 x 1 litre opaque high density polyethylene bottles with high density polyethylene screw caps.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10397/015/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1998

Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

October 2016