SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tiamvet Solution 12.5% w/v Oral Solution for use in Drinking Water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition for 1 ml:
Active substance:
Tiamulin hydrogen fumarate ..... 125.0 mg
Equivalent to
Tiamulin ..... 101.2 mg

Excipient:
Benzyl alcohol..... 15.0 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution for use in drinking water.
Clear, colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

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.

4.3 Contra-indications

Do not administer products containing monensin, salinomycin or narasin during or for at least 7 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, including special precautions to be taken by the person administering the medicinal product to the animals

i. Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.

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

Do not eat, drink or smoke whilst using this product.
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.

4.7 Use during pregnancy, lactation or lay

The product can be used in pregnant and lactating pigs.

4.8 Interaction with other medicinal products and other forms of interaction

See section 4.3, “Contraindications”.

4.9 Amounts to be administered and administration route

Oral use. Administer in drinking water.

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.
To ensure an intake of 8.8 mg/kg daily it is important to know the weight of the animals to be treated and to measure accurately their drinking water consumption.

Administer the calculated dose (based on the animals weight) in approximately one half of the daily water requirements, to ensure consumption of the correct dose. Unmedicated water should then 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.

Where a water medicator is used the appropriate stock solution should be made up according to the makers instructions.
Any medicated water not consumed within 24 hours should be discarded.
If there is no response to treatment within 5 days, the diagnosis should be re-established.

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.

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

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

Pigs (meat and offal): 2 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Other antibacterials, Pleuromutilins

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 antimicrobial and the following organisms show sensitivity *in-vitro*:

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

Tiamulin is rapidly absorbed after oral administration. It concentrates in some tissues e.g. lungs and is rapidly metabolised an excreted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol.
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.
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

No special precautions for storage.

6.5 Nature and composition of immediate packaging

Material of the primary container
Polyethylene high density bottles closed with polypropylene caps fitted with a polypropylene dosing device and poly vinyl chloride/vinyl acetate seal.

Dosing device
Polypropylene measuring cup.

Pack sizes
500 ml bottle
1litre bottle
2 litres bottle

5 litres bottle

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

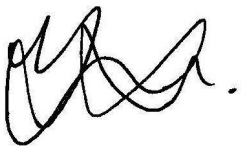
Vm 15052/4028

9. DATE OF THE FIRST AUTHORISATION

14 September 2007

10. DATE OF REVISION OF THE TEXT

October 2022



Approved : 07 October 2022