MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

500 ml, 1 l, 2 l and 5 l bottles.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release: Ceva Sante Animale,Zone Industrielle de Tres-le-Bois, 22600 Loudeac, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tiamvet Solution 12.5% w/v oral solution for use in drinking water

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Tiamulin hydrogen fumarate	125.0 mg/ml
Equivalent to Tiamulin	101.2 mg/ml

Preservative:
Benzyl alcohol ..... 15.0 mg/ml

4. PHARMACEUTICAL FORM

Oral solution for use in drinking water

5. PACKAGE SIZE

500 ml, 1 litre, 2 litres or 5 litres.

6. INDICATION(S)

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

7. CONTRAINDICATIONS

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.

8. ADVERSE REACTIONS

On rare occasions erythema or mild oedema of the skin may occur in pigs following the use of tiamulin hydrogen fumarate.

9. TARGET SPECIES

Pigs

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 or administer continuously at a level of 60 ppm of active substance in the drinking water, as the only source of drinking water at the rate of 9.6 ml solution/ 20 litres (4.5 gallons) water.

Any medicated water not consumed within 24 hours should be discarded.

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

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.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat and offal: 2 days.

13. SPECIAL STORAGE PRECAUTIONS

No special precautions for storage.

14. SPECIAL WARNING(S)

SPECIAL WARNINGS FOR THE 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.

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

USER WARNINGS: 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.

PREGNANCY AND LACTATION: The product can be used in pregnant and lactating pigs.

INTERACTIONS : 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.

OVERDOSE: 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.

15. EXPIRY DATE

Do not use after the expiry date stated on the bottle. Once broached, use by:...

Dispose of used product 3 months after first opening. Dispose of used product 24 hours after dilution in drinking water.
When the container is opened for the first time, using the specified in-use shelf life, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided.

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

October 2022

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V
To be supplied only on veternary prescription.

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

20. MARKETING AUTHORISATION NUMBER(S)

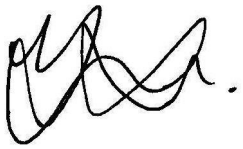
Vm 15052/4028

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

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.*



Approved : 07 October 2022