

# **PACKAGING, LABELLING AND PACKAGE LEAFLET**

## Label-leaflet

**DISENTIN 125 mg/ml ORAL SOLUTION [CZ, HU, PL, RO, SK, EL]  
MAYMULINA 125 mg/ml Oral solution [ES, PT]  
Tiamulin hydrogen fumarate**

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

Marketing authorisation holder:

**[CZ, HU, PL, RO, SK, EL]:**

VETPHARMA ANIMAL HEALTH, S.L.  
Les Corts, 23  
08028 – BARCELONA  
Spain

**[ES, PT]:**

LABORATORIOS MAYMÓ, S.A.  
Vía Augusta, 302  
08017 – BARCELONA  
Spain

Manufacturer responsible for batch release:

LABORATORIOS KARIZOO, S.A.  
Polígono Industrial La Borda  
Mas Pujades, 11-12  
08140 – CALDES DE MONTBUI (Barcelona)  
Spain

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

DISENTIN 125 mg/ml Oral solution [CZ, HU, PL, RO, SK, EL]  
MAYMULINA 125 mg/ml Oral solution [ES, PT]  
Tiamulin hydrogen fumarate

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

Composition per ml:

**Active substance:**

Tiamulin hydrogen fumarate.....125.0mg

**Excipients:**

Propyl parahydroxybenzoate.....0.1mg

Methyl parahydroxybenzoate (E-218) .....0.9 mg

**4. PHARMACEUTICAL FORM**

Oral solution

Clear and colourless solution

**5. PACKAGE SIZE**

1-L bottles

**6. TARGET SPECIES**

Pig (all categories)

Chickens (broilers, pullets, laying hens and breeding birds)

Turkeys (poult and breeding turkeys)

**7. INDICATIONS**

**Pigs**

i) Treatment of pig dysentery caused by strain of *Brachyspira hyodysenteriae* and complicated by strains of *Fusobacterium* spp. and *Bacteroides* spp.

ii) Treatment of porcine respiratory disease complex (PRDC) caused by *M. hyopneumoniae* and viruses such as PRRS and flu in pigs complicated by *P. multocida* and *A. pleuropneumoniae* bacteria.

iii) Treatment of pleuropneumonia caused by *A. pleuropneumoniae*.

**Chickens**

Treatment and prevention of chronic respiratory diseases (CRD) and air sacculitis caused by *M. gallisepticum* and *M. synoviae*.

**Turkeys**

Treatment and prevention of infections sinusitis and air sacculitis caused by *M. gallisepticum*, *M. synoviae* and *M. meleagridis*.

## 8. CONTRAINDICATIONS

Do not use monensin, narasin or salinomycin during or for at least seven days before or after treatment with tiamulin. This may result in severe growth depression or death.

## 9. ADVERSE REACTIONS

Occasionally erythema and other hypersensitivity reactions can occur in pigs. In these cases symptomatic therapy is indicated.

While administering tiamulin to poultry, the consumption of water may fall. This depends on the concentration: the 0.0125% concentration of tiamulin may result in 10% lower consumption of water, while the concentration of 0.025% may decrease the consumption by 15%. No negative effects on the overall condition of the poultry or the overall effectiveness of the product are to be expected; however, the water consumption should be monitored frequently, especially during hot weather.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 10. METHOD AND ROUTE OF ADMINISTRATION

### Pigs

#### i) Treatment of dysentery in pigs

The dose is 8.8 mg tiamulin hydrogen fumarate per kg bodyweight daily administered in the drinking water to pigs for 3 to 5 consecutive days. The dose is normally achieved at concentration of 0.006% tiamulin hydrogen fumarate (60 mg/1 litre) in drinking water.

#### ii) Additional therapy of PRDC caused by *M. hyopneumoniae* and various viruses and complicated *P. multocida* and *A. pleuropneumoniae*.

The dose is 15.0-20.0 mg tiamulin hydrogen fumarate per kg bodyweight daily administered for 5 to 10 consecutive days; the dose is normally achieved at concentration of 0.012-0.018% tiamulin hydrogen fumarate (120-180 mg/ 1 litre) in drinking water.

#### iii) Treatment of pleuropneumonia caused by *A. pleuropneumoniae*.

The dose is 20.0 mg tiamulin hydrogen fumarate per kg bodyweight daily administered for 5 consecutive days; the dose is normally achieved at concentration of 0.018% tiamulin hydrogen fumarate (180 mg/ 1 litre) in drinking water.

### Chickens

i) Prevention of chronic respiratory diseases (CRD) and air sacculitis caused by *M. gallisepticum* and *M. synoviae*.

Broilers: 0.0125%-0.025% tiamulin hydrogen fumarate (125 mg-250 mg/1 litre) in drinking water for 3 days during first week of life and thereafter for 1-2 days every 3-4 weeks, according to risk.

Replacement pullets: 0.0125%-0.025% tiamulin hydrogen fumarate (125 mg-250 mg/1 litre) in drinking water for 3 days during the first week of life, thereafter 1-2 days every 4-6 weeks according to the level of risk.

Laying and breeding hens: 0.0125%-0.025% tiamulin hydrogen fumarate (125 mg-250 mg/1 litre) in drinking water for 3 days every 4 weeks from the start of laying according to the level of risk.

ii) Treatment of chronic respiratory diseases (CRD) and air sacculitis caused by *M. gallisepticum* and *M. synoviae* in broilers, replacement pullets, layers and breeding hens. Tiamulin hydrogen fumarate 0.025% (250 mg/1 litre) in drinking water during 3-5 days.

Tiamulin hydrogen fumarate in 0.025% concentration in drinking water provides the following doses according to the age of animals:

4-week old broiler:	30 mg/kg of bodyweight
10-week old pullets:	30 mg/kg of bodyweight
Laying hen:	25 mg/kg of bodyweight

### **Turkeys**

i) Prevention of infectious sinusitis and air sacculitis caused by *M. gallisepticum*, *M. synoviae* and *M. meleagridis*.

Turkey poults (growers) – 0.025% tiamulin hydrogen fumarate (250 mg/1 litre) in drinking water for 3 days during the first week of life and thereafter 1-3 days every 4-6 weeks according to the level of risk.

Turkeys breeders – 0.025% tiamulin hydrogen fumarate (250 mg/1 litre) in drinking water for 3-5 days every 4 weeks according to the level of risk.

ii) Treatment of infectious sinusitis and air sacculitis caused by *M. gallisepticum*, *M. synoviae* and *M. meleagridis*.

Tiamulin hydrogen fumarate 0.025% (250 mg/ 1 litre) in drinking water for 3-5 days.

Tiamulin hydrogen fumarate in 0.025% concentration in drinking water will provide the following daily dosage depending on the age of the turkey:

1-week old poult:	70 mg/kg of bodyweight
4-week old poult:	50 mg/kg of bodyweight

8-week old poult: 25-30 mg/kg of bodyweight  
20-week old poult: 20 mg/kg of bodyweight

Mixing 2.0 ml of product with 1 litre of water results in 0.025% solution of tiamulin hydrogen fumarate and mixing 1.0 ml of the product with 1 litre of water results in 0.0125% tiamulin hydrogen fumarate solution.

If adding the product into large volumes of water, please start by preparing a concentrated solution and then dilute it to the required concentration.

Fresh solution of tiamulin-medicated drinking water should be made up each day.

## 11. **ADVICE ON CORRECT ADMINISTRATION**

None

## 12. **WITHDRAWAL PERIOD**

### **Pigs**

Meat and offal: 4 days

### **Chickens**

Meat and offal: 2 days

Eggs: Zero days

### **Turkeys**

Meat and offal: 5 days

## 13. **SPECIAL WARNINGS, IF NECESSARY**

### **Special precautions for use in animals**

Freshly medicated water must be prepared daily. Watering equipment should be inspected and cleaned prior to addition of the product.

Whenever possible, use of the product should be based on the results of susceptibility testing and take into account the epidemiological information on resistance (regional, farm level) and national policies with respect to use of antimicrobials.

Use of the product deviating from the information given within SPC can cause increase of prevalence of bacteria resistant to tiamulin.

If there is no response to treatment within 5 days, the diagnosis should be re-established.

Use of the product should be combined with the good farming practice, e.g. good zoohygiene, proper ventilation, avoiding of overstocking.

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

Avoid contact with skin, eyes and mucous membranes.

Personal protective equipment consisting of protective goggles and rubber or latex gloves should be worn when handling the veterinary medicinal product. In case of accidental contact with skin or mucous membranes rinse affected area immediately with plenty of water and remove contaminated clothing, which is in direct contact with the skin. In case of accidental contact with eyes, rinse the eye immediately with plenty of fresh water. If irritation occurs seek medical advice and show the package leaflet or the label to the physician. In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.

People with known hypersensitivity to tiamulin should handle the product with caution.

Wash hands after use.

### **Interaction with other medicinal products and other forms of interaction**

In order to prevent interaction of incompatible ionophores monensin, narasin and salinomycin in pigs, it should be ensured that these effective agents are not contained in the feed and that there was no contamination of the feed with these agents.

For chickens and turkeys, to avoid interactions between the incompatible ionophores monensin, narasin and salinomycin and tiamulin, the feed mill supplying the birds 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.

### **Overdose (symptoms, emergency procedures, antidotes), if necessary**

Single oral doses of 100 mg/kg bodyweight in pigs caused hyperpnoea and abdominal discomfort. At 150 mg/kg no CNS effects were noted except for tranquillisation. At 55 mg/kg given for 14 days, a transient salivation and slight gastric irritation occurred. Tiamulin is considered to have an adequate therapeutic index in the pig and a minimum lethal dose has not been established.

Tiamulin has a relative wide therapeutic index, with a low risk of overdose mainly due to the fact that abnormally high concentrations result in decreased water consumption and hence decreased consumption of tiamulin. LD<sub>50</sub> for chicken is 1290 mg/kg bodyweight and for turkeys 840 mg/kg bodyweight.

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

Should the symptoms of intoxication appear, remove the medicated water immediately and replace it with fresh water.

### **Incompatibilities**

None known

**14. EXPIRY DATE**

EXP: {month/year}

Once opened, use by ...

Shelf life after first opening the container: 6 months.

Shelf life after dilution according to directions: 24 hours.

**15. SPECIAL STORAGE CONDITIONS**

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

**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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required.

These measures should help to protect the environment.

**For animal treatment only**

**Keep out of the sight and reach of children**

**To be supplied only on veterinary prescription**

**Date on which the package leaflet was last approved:**

**Marketing authorization number:**

**Batch: {number}**