

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 200 mg/ml solution for injection.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

#### **Active substance**

Tiamulin base 162.2 mg  
(equivalent to tiamulin hydrogen fumarate 200.0 mg)

#### **Excipients**

Ethanol 50.0 mg

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Solution for injection.  
A clear, yellow, oily solution.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Porcine.

#### 4.2 Indications for use, specifying the target species

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

For the treatment of enzootic pneumonia and mycoplasmal arthritis.

#### 4.3 Contraindications

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

#### 4.4 Special warnings for each target species

For intramuscular injection of pigs only.

## 4.5 Special precautions for use

### Special precaution(s) for use in animals

None.

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

Ensure dry syringe is used.

Accidental self-injection of oily preparations may cause serious localised reactions. If accidental injection occurs go immediately to the casualty department of the nearest hospital as special treatment may be necessary. Take the pack or package leaflet to show the doctor, who should be informed that the product contains oil.

## 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.

## 4.7 Use during pregnancy, lactation or lay

The product 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 the product. Severe growth depression or death may result.

## 4.9 Amounts to be administered and administration route

Intramuscular injection only. Ensure dry syringes only are used. The closures must not be breached more than 33 times. In order to prevent excessive breaching of the stopper, a suitable multiple dosing device should be used.

*For the treatment of clinical swine dysentery*

1 ml per 20 kg (equivalent to 10 mg tiamulin hydrogen fumarate per kg bodyweight) to be administered in a single treatment followed by tiamulin in the water or feed.

*For the treatment of enzootic pneumonia or mycoplasmal arthritis*

1.5 ml/20 kg bodyweight (equivalent to 15 mg tiamulin hydrogen fumarate per kg bodyweight) daily for 3 consecutive days.

The maximum volume to be administered at any one intramuscular injection site should not exceed 10 ml.

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

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

## 4.11 Withdrawal Period(s)

Meat and offal: 22 days

## 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>B. hyodysenteriae</i>
Mycoplasma	<i>M. hyopneumoniae</i> (syn <i>M. suis</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</i> spp.
Leptospira	<i>Leptospira</i> spp.
Gram-Positive	<i>Staphylococcus</i> spp., <i>Streptococcus</i> spp. <i>Actinomyces</i> ( <i>Corynebacterium</i> ) <i>pyogenes</i> .
Gram-Negative	<i>Klebsiella pneumoniae</i> , <i>Actinobacillus</i> ( <i>Haemophilus</i> ) spp., <i>Fusobacterium</i> <i>necrophorum</i> , <i>Campylobacter coli</i> , <i>Bacteroides</i> spp., <i>Pasteurella</i> spp.

### 5.2 Pharmacokinetic properties

Tiamulin 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

Ethanol  
Sesame Oil

### 6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

Shelf-life after first opening the immediate packaging: 28 days.

#### **6.4 Special precautions for storage**

Store below 30°C.  
Do not refrigerate.  
Protect from light.

#### **6.5 Nature and composition of immediate packaging**

Clear 100 ml Type III glass vial, sealed with a red bromobutyl rubber stopper and an aluminium cap containing a sterile pale yellow oily solution, supplied in a carton.

#### **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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RG24 9NL  
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### **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10397/019/001

### **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> October 1998  
Date of last renewal: 30<sup>th</sup> September 2008

### **10 DATE OF REVISION OF THE TEXT**

October 2016