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 provides tiamulin base equivalent to 200 mg tiamulin hydrogen fumarate.
Tiamulin hydrogen fumarate 200 mg/ml

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow oily solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Swine dysentery: For the treatment of swine dysentery caused by *Brachyspira hyodysenteriae* and complicated by *Bacteroides* spp and *Fusobacterium* spp.
Enzootic pneumonia complex of pigs: For the treatment of enzootic pneumonia complex, caused by *M. hyopneumoniae* and where the secondary bacteria are sensitive to tiamulin.
Mycoplasmal arthritis: For the treatment of arthritis caused by *Mycoplasma hyosynoviae,* to reduce lameness and restore growth performance.

4.3 Contraindications

Animals should not receive products containing monensin, narasin or salinomycin during or for at least seven days before and after treatment with Denagard 200 Solution for Injection. Severe growth depression or death may result.

4.4 Special warnings for each target species

For intramuscular use only in pigs.

4.5 Special precautions for use

i. Special precautions for use in animals

As Denagard 200 Solution for Injection 200 mg/ml is formulated with sesame oil, it is important to ensure that the syringe used is dry. The admixture of oil and water may cause the plunger to stick.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
In case of skin contact with the product, wash immediately with running water in order to minimise absorption through the skin.
In case of eye contact with the product, wash immediately with running water and seek medical advice.

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 this product.

4.7 Use during pregnancy, lactation or lay

Can be use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Animals should not receive products containing monensin, narasin or salinomycin during or for at least seven days before and after treatment with Denagard 200 Solution for Injection. Severe growth depression or death may result.

4.9 Amounts to be administered and administration route

To be administered by intramuscular injection. Swab the rubber septum before removing each dose. Use a dry, sterile, needle and syringe. The maximum volume to be administered at any one intramuscular injection site should not exceed 10 ml. Swine dysentery Treatment: The dose is 1 ml/20 kg bodyweight (equivalent to 10 mg tiamulin hydrogen fumarate/kg body weight) intramuscularly administered as a single treatment to pigs showing clinical signs of the disease.
Follow-up treatment should be provided when necessary with either Denagard 12.5% w/v Concentrate for Oral Solution or Denagard 2% Premix for Medicated Feedingstuff administered according to directions in the drinking water or in the feed, respectively.
Enzootic pneumonia complex of pigs Treatment: The dose is 1.5 ml/20 kg bodyweight (equivalent to 15 mg tiamulin hydrogen fumarate/kg body weight) administered intramuscularly for a period of 3 consecutive days to pigs showing clinical signs of the disease.

Mycoplasmal arthritis Treatment: The dose is 1.5 ml/20 kg bodyweight (equivalent to 15 mg tiamulin hydrogen fumarate/kg body weight) administered intramuscularly for a period of 3 consecutive days to pigs showing clinical signs of the disease.

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

Pleuromutilins have a wide margin of safety. Do not exceed the specified dosage.

4.11 Withdrawal period(s)

Meat and offal: 28 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use.

ATCVet Code: QJ01XQ01

5.1 Pharmacodynamic properties

The following organisms show sensitivity to tiamulin *in vitro:*
Brachyspira: *Brachyspira hyodysenteriae, Brachyspira pilosicoli*
Mycoplasmas: *Mycoplasma hyopneumoniae, M. hyorhinis, M. hyosynoviae, M. dispar,Ureaplasma spp,*Gram-positive: *Staphylococcus spp., Streptococcus spp., Corynebacterium pyogenes.*
Gram-negative: *Pasteurella spp., Klebsiella pneumoniae, Actinobacillus (Haemophilus)spp., Fusobacterium necrophorum, Bacteroides spp., Campylobacter coli,Lawsonia intracellularis.*

5.2 Pharmacokinetic particulars

Following oral administration the active ingredient, tiamulin, is rapidly absorbed, peak serum levels being achieved within two hours. Tiamulin distributes widely in tissues, including the colon. High tiamulin concentrations are found in the lung of up to approximately 20 times the value found in the serum. Two hours post-injection, tiamulin lung levels of 14.5 – 16.7 mg/g have been found.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Sesame oil

6.2 Incompatibilities

None known.

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

Do not store above 25°C. Do not refrigerate.
This product does not contain an antimicrobial preservative. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

100 ml Type III glass vial, closed with a rubber stopper with aluminium seal.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4053

9. DATE OF FIRST AUTHORISATION

31 July 1985

10. DATE OF REVISION OF THE TEXT

October 2020

Approved: 22 October 2020