ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

25 kg Bag label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Denagard 80% w/w

800 mg/g Premix for medicated feed for pigs, chickens and turkeys

Tiamulin hydrogen fumarate

2. STATEMENT OF ACTIVE SUBSTANCES

<see product name>

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

<25 kg>

5. TARGET SPECIES

Pigs
Chickens (broiler, replacement pullet, layer/breeder)
Turkeys (poult (grower) and breeder)

6. INDICATION(S)

Pigs
For the treatment and metaphylaxis, when the disease is present in the group, of swine dysentery caused by *Brachyspira hyodysenteriae* susceptible to tiamulin. The presence of the disease in the group must be established before the product is used.
For the treatment of colitis caused by *Brachyspira pilosicoli.*
For the treatment of ileitis caused by *Lawsonia intracellularis.*
For the treatment of enzootic pneumonia caused by *Mycoplasma hyopneumoniae.*

Chickens (broiler, replacement pullet, layer/breeder)
For the treatment and prevention of chronic respiratory disease (CRD) and air sacculitis caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.

Turkeys (poult (grower) and breeder)
For the treatment and prevention of infectious sinusitis and air sacculitis caused by *Mycoplasma gallisepticum, Mycoplasma meleagridis* and *Mycoplasma synoviae.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Calculations to achieve the correct dose rate and achieve the correct inclusion rate should be based on:
- Inclusion rate (ppm) = dose rate (mg/kg bodyweight) x bodyweight (kg) / daily feed intake (kg).

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tiamulin hydrogen fumarate has to be adjusted accordingly.

Pigs
Treatment and metaphylaxis of swine dysentery caused by *B. hyodysenteriae*, treatment of porcine colonic spirochaetosis (colitis) caused by *B. pilosicoli*
Dosage: 5 - 10 mg tiamulin hydrogen fumarate/kg bodyweight daily administered for 7 to 10 consecutive days. The dosage will normally be achieved by an inclusion level of 100 – 200 ppm tiamulin hydrogen fumarate in the finished feed provided that feed intake is unaffected.

Amount of THF (mg/g) per premix formulation	Amount of premix formulation per one tonne of feed
800.0	0.125 – 0.25 kg

Treatment of porcine proliferative enteropathy (ileitis) caused by *L. intracellularis*
Dosage: 7.5 mg tiamulin hydrogen fumarate/kg bodyweight daily administered for 10 to 14 consecutive days. The dosage will normally be achieved by an inclusion level of 150 ppm tiamulin hydrogen fumarate in the finished feed providing that feed intake is unaffected.

Amount of THF (mg/g) per premix formulation	Amount of premix formulation per one tonne of feed
800.0	0.188 kg

Treatment of enzootic pneumonia caused by *M. hyopneumoniae*
Dosage: 5.0 – 10.0 mg tiamulin hydrogen fumarate/kg bodyweight daily administered for 7 to 10 consecutive days. The dosage will normally be achieved by an inclusion level of 100 - 200 ppm tiamulin hydrogen fumarate in the finished feed provided that feed intake is unaffected.

Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

Amount of THF (mg/g) per premix formulation	Amount of premix formulation per one tonne of feed
800.0	0.125 – 0.25 kg

Chickens (broiler, replacement pullet, laying and breeding hens)
Treatment and prevention of chronic respiratory disease (CRD) caused by *M. gallisepticum* and air sacculitis and infectious synovitis caused by and *M. synoviae*.

Dosage – Treatment and prevention: 25 mg tiamulin hydrogen fumarate/kg bodyweight daily administered for the period of 3 to 5 consecutive days. This is normally achieved by an inclusion level of 250 - 500 ppm tiamulin hydrogen fumarate in finished feed provided that feed intake is unaffected. Inclusion levels in the higher range will in most cases be needed to avoid underdosing. In fast growing birds, e.g. broiler chickens during the first 2 to 4 weeks of life, inclusion levels in the lower range may be sufficient.

Amount of THF (mg/g) per premix formulation	Amount of premix formulation per one tonne of feed
800.0	0.313 - 0.625 kg

Turkeys (young poults, breeding turkeys)
Treatment and prevention of infectious sinusitis and air sacculitis caused by *M. gallisepticum*, *M. synoviae* and *M. meleagridis*.
Dosage – Treatment and prevention: 40 mg tiamulin hydrogen fumarate/kg bodyweight daily administered for the period of 3 to 5 consecutive days. This is normally achieved by an inclusion level of 250-500 ppm tiamulin hydrogen fumarate in finished feed provided that feed intake is unaffected. Inclusion levels in the higher range will in most cases be needed to avoid underdosing. In fast growing birds, e.g. poults during the first 2 to 4 weeks of life, inclusion levels in the lower range may be sufficient.

Amount of THF (mg/g) per premix formulation	Amount of premix formulation per one tonne of feed
800.0	0.313 – 0.625 kg

Preventive treatment with tiamulin should only be initiated after confirmed infection with *M. gallisepticum*, *M. synoviae* or *M. meleagridis* and then as an aid in the prevention strategy to reduce the clinical signs and mortality from respiratory disease in flocks, where infection in ovum is likely because the disease is known to exist in the parent generation. The prevention strategy should include efforts to eliminate the infection from the parent generation.

8. WITHDRAWAL PERIOD(S)

Pigs
Treatment (at 5 to 10 mg/kg bodyweight): Meat and offal: 6 days

Chickens
Meat and offal: 1 day
Eggs: 0 days

Turkeys
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications
Animals should not receive products containing ionophores (monensin, narasin or salinomycin) during or for at least 7 days before or after treatment with tiamulin. Severe growth depression or death may result.

Warnings
In case of reduced feed intake, the inclusion levels in feed may need to be increased to achieve target dosage. Acute cases and severely diseased animals with reduced feed intake should be treated with a product of suitable formulation such as an injectable or water solution.
It is sound clinical practice to base treatment on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria.

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

Use during pregnancy, lactation or lay
Can be used in pigs during pregnancy and lactation.
Can be used in laying and breeding chickens and turkeys.

Interactions
Tiamulin has been shown to interact with ionophores such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin during or at least 7 days before or after treatment with tiamulin. Severe growth depression, ataxia, paralysis or death may result.
If signs of an interaction do occur, administration of contaminated feed should be stopped immediately. The feed should be removed and replaced with fresh feed not containing the anticoccidials monensin, salinomycin or narasin.

Overdose
Pigs: 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 sedation. At 55 mg/kg given for 14 days a transient salivation and slight gastric irritation occurred. A minimum lethal dose has not been established in pigs.

Chickens and turkeys: The LD_5 for chickens is 1290 mg/kg and turkeys 840 mg/kg bodyweight.
The clinical signs of acute toxicity in chickens are - vocalization, clonic cramps and lateral recumbency. In turkeys signs of acute toxicity include clonic cramps, lateral or dorsal recumbency, salivation and ptosis.
If signs of intoxication do occur promptly remove the medicated feed, replace with fresh unmedicated feed and apply supportive, symptomatic therapy.

Operator warnings
When mixing the veterinary medicinal product and handling the medicated feed, direct contact with eyes, skin and mucous membranes should be avoided. Personal protective equipment should be worn when mixing the veterinary medicinal product or handling the medicated feed: overalls, impervious gloves and either a disposable

half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator conforming to European Standard EN 140, with a filter to European Standard EN 143. Wash contaminated skin.

In case of accidental ingestion, seek medical advice immediately and show the label to the physician.

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

10. EXPIRY DATE

Exp date: <mm yyyy>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

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

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V To be supplied only under veterinary prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

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

Marketing authorisation holder:

Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL
Tel: 01256 353131

Manufacturers responsible for batch release:

Sandoz GmbH
Plant Schaftenau
Biochemiestrasse 10
A-6250 Kundl
Austria

Elanco France
26, rue de la Chapelle
68330 Huningue
France

16. MARKETING AUTHORISATION NUMBER(S)

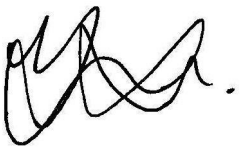
Vm 00879/4054

17. MANUFACTURER'S BATCH NUMBER

Lot Nr <number>

OTHER INFORMATION

Date of last revision of the label:



Approved: 03 March 2021