Pharmasin® 250 mg/g Premix

Medicated feeding stuff for poultry

- **HOMOGENEITY** of the active in the feed is crucial to ensure a correct dosing
- **ANTIMICROBIAL ACTIVITY** is the real activity against the targeted pathogens
- **STABILITY** is essential for treatment and depends mainly on the granule formulation

HOMOGENEITY

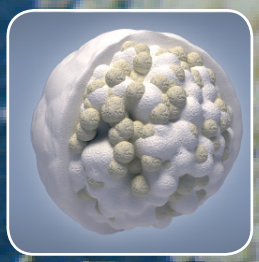
Pharmasin® premix consists out of equal sized microgranulated granules

= Correct dose

ANTIMICROBIAL ACTIVITY

Pharmasin® has the highest antimicrobial activity

= Efficacy



STABILITY

Is guaranteed by using Microgranulation technology, protecting the antimicrobial activity

= Stability

- **Indications**
  Respiratory : *Mycoplasma spp*
  Gastro-intestinal: Necrotic enteritis
- ***Mycoplasma spp*** : 127 mg per kg bodyweight for 5 days
  Necrotic enteritis: 10-20 mg per kg bodyweight for 7 days
- **Withdrawal time**: 1 day

HUVEPHARMA®

We add performance to your business

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QUALITATIVE AND QUANTITATIVE COMPOSITION

Tylosine (as tylosin phosphate):
250 mg per g (equivalent to 250 000 IU)
Excipients: Wheat meal, dipotassium phosphate, pregelatinized starch

PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
Light tan coloured, free flowing granules.

TARGET SPECIES

Pigs, broilers and pullets.

INDICATIONS FOR USE (SPECIFYING THE TARGET SPECIES)

Pigs:

Treatment and prevention of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellularis* when the disease has been diagnosed at the group or herd level.

Broilers and pullets:

Treatment and prevention of respiratory infections caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae*, when the disease has been diagnosed in the flock.

Treatment and prevention of necrotic enteritis caused by *Clostridium perfringens*, when the disease has been diagnosed in the flock.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Administration through the feed: for the preparation of a medicated feed containing 40-1100 gram tylosine per ton of feed, the required amount of Pharmasin 250 mg/g Premix should be homogenously mixed with a suitable carrier into a feed premixture so that at least 5 kg of this premixture can be added to the feed in order to obtain a medicated feed with the required concentration.
For the preparation of medicated feed:
As 1 kg Pharmasin 250 mg/g premix contains 250 g tylosin activity it follows that 4 mg Pharmasin 250 mg/g premix corresponds to 1 mg tylosin activity. The dosages are as follows:

Pigs: For the treatment and prevention of porcine intestinal adenomatosis (PIA):
4-5 mg tylosin per kg BW (corresponding to 16-20 mg Pharmasin 250 mg/g premix per kg BW) for 3 weeks.
or
8-10 mg tylosin per kg BW (corresponding to 32-40 mg Pharmasin 250 mg/g premix per kg BW) for 8 days, followed by 4-5 mg tylosin per kg BW (corresponding to 16-20 mg Pharmasin 250 mg/g premix per kg BW) until the end of the period of risk.

Broilers and pullets:

For the treatment and prevention of respiratory infections:
127 mg tylosin per kg BW (corresponding to 508 mg Pharmasin 250 mg/g premix per kg BW) for the first 5 days of life. It is strongly recommended to repeat the treatment of the birds at the age of 3-4 weeks.

For the treatment and prevention of necrotic enteritis:
10-20 mg tylosin per kg BW (corresponding to 40-80 mg Pharmasin 250 mg/g premix per kg BW) for 7 days.
For the preparation of the medicated feed the body weight of the animals to be treated and their actual daily feed consumption should be taken into due account. Consumption may vary depending on factors like age, breed, husbandry system. To provide the required amount of active substance in mg per kg mixed feed the following calculation should be made:
The mixing should be performed by an (authorised) feedingstuff manufacturer with adequate mixing apparatus.
The uptake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of tylosin should be adjusted accordingly.
Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered.

$$\text{...mg Pharmasin 250 mg/g premix per kg/ mixed feed} = \frac{\text{.... mg Pharmasin 250 mg/gpremix/kg BW/day} \times \text{average body weight (kg) of the animals to be treated}}{\text{Average daily amount of mixed feed intake /kg per animal}}$$

WITHDRAWAL PERIOD(S)

Meat & offal
Pig: Zero days
Broilers and pullets: 1 day
Do not use in laying hens producing eggs for human consumption.

PHARMACODYNAMIC PROPERTIES

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible micro-organisms.
The tylosin spectrum of activity includes Gram-positive bacteria, some Gram–negative strains such as *Pasteurella*, and *Mycoplasma spp.* at concentrations of 16 µg/ml or less.

PHARMACOKINETIC PARTICULARS

In most species peak plasma concentrations have been attained 1 to 2 hours after administration of tylosin. Compared to plasma levels clearly higher tissue concentrations have been observed. Tylosin was extensively metabolized. Most of the residues are excreted in faeces predominantly consisting of tylosin A, tylosin factor D and dihydrodesmycosin.

SHELF LIFE

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after incorporation into meal or pelleted feed: 3 months.

SPECIAL PRECAUTIONS FOR STORAGE

Store in the original container to protect from light. Store in a dry place. Store below 30°C. Do not refrigerate or freeze. Protect from frost.

NATURE AND COMPOSITION OF IMMEDIATE PACKING

Low-density polyethylene/ paper – paper - paper bag of 5 and 20 kg with sutured crimp.
1 kg PE/Alu/PET bag
Not all packs may be marketed.

MARKETING AUTHORISATION HOLDER

Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerpen, Belgium

MARKETING AUTHORISATION NUMBER

Vm 30282/4009

DATE OF FIRST AUTHORISATION

20 October 2009

DATE OF REVISION OF THE TEXT

January 2012

** A full SPC is available upon request*

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