

Pharmasin® 100 mg/g
Premix for Medicated Feeding Stuff
 Keep out of reach of children.

STATEMENT OF ACTIVE SUBSTANCE:

Tylosin (as tylosin phosphate):
 100 mg per g. (equivalent to
 100 000 IU)

PRODUCT DESCRIPTION:

Pharmasin® 100 mg/g Premix for Medicated Feeding Stuff for Pigs, Broilers and Pullets represents light tan coloured, free flowing granules.

PHARMACODYNAMICS:

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.*

PHARMACOKINETICS:

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.

INDICATIONS FOR USE:

Pigs: Treatment and prevention of Porcine Intestinal Adenomatosis (PIA) 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.

RECOMMENDED DOSAGE AND MODE OF ADMINISTRATION:

Administration through the feed: for the preparation of a medicated feed containing 40-200 gram tylosine per ton of feed, the required amount of product 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 of product contains 100 g tylosin activity it follows that 10 mg

Pharmasin 100 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 40 - 50 mg product per kg BW) for 3 weeks.

Broilers and pullets:

For the treatment and prevention of respiratory infections:

127 mg tylosin per kg BW (corresponding to 1270 mg product 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 100 – 200 mg product 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:

$$\frac{* \dots \text{mg product} / \text{kg BW/day} \times \text{average body weight (kg) of the animals to be treated}}{\text{Average daily amount of mixed feed intake /kg per animal}} = \dots \text{mg product per kg/ mixed feed}$$

The mixing should be performed by an (authorised) feeding stuff 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. Body weight should be evaluated accurately to avoid under dosing.

CONTRAINDICATIONS:

Do not use in animals with known sensitivity to the active substance and/or to any of the excipients of the veterinary medicinal product.

Do not use in animals with known hyper sensitivity to tylosin and other macrolides.

Do not use where cross-resistance to other macrolides (MLS-resistance) is suspected.

Do not use in animals vaccinated with tylosin-sensitive vaccines either at the same time or within 1 week previously.

Do not use in animals with hepatic disorders.

Do not use in horses. Danger of inflammation of the cecum.

WARNINGS AND PRECAUTIONS:

Special precautions for use in animals
 Animals with acute infections may have a reduced feed intake and should be treated with a suitable injectable product first. Due to likely variability (time, geographical) in susceptibility of bacteria for tylosin, bacteriological sampling and susceptibility testing are recommended.

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to Tylosin and other macrolides.

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

Tylosin may induce irritation.

Macrolides, such a tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided.

To avoid exposure during preparation of the medicated feed, wear overalls, safety glasses, impervious gloves, and wear either a disposable half

mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143. Wash hands after use.

In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water.

Do not handle the product if you are allergic to ingredients in the product. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

INTERACTIONS WITH OTHER MEDICAMENTS:

Lincosamides and aminoglycoside antibiotics antagonise the activity of tylosin.

STATEMENT ON USAGE DURING PREGNANCY AND LACTATION:

Laboratory studies in mice and rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. No studies have been conducted in the target species

population. Use only according to the benefit/risk assessment by the responsible veterinarian.

ADVERSE EFFECTS/ UNDESIRABLE EFFECTS:

In pigs, adverse reactions have been observed, including diarrhoea, pruritus, erythema, rectal oedema and prolapse.

OVERDOSE AND TREATMENT:

Tylosin has been shown to produce no adverse effects when fed to pigs at 600 ppm in the feed (three to six times the recommended dose level) for 28 days. At high levels diarrhoea, apathy, convulsions may occur. The therapy is symptomatic.

INCOMPATIBILITIES:

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

WITHDRAWAL PERIODS:

Meat & offal:

Pig: 0 days

Broilers and pullets: 1 day

Do not use in laying hens producing eggs for human consumption.

DISPOSAL

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

SHELF-LIFE OF THE VETERINARY PRODUCT AS PACKAGED FOR SALE: 2 years.

SHELF LIFE AFTER FIRST OPENING OF THE CONTAINER:

3 months.

SHELF LIFE AFTER INCORPORATION INTO MEAL OR PELLETTED FEED: 3 months.

STORAGE CONDITIONS:

Store in the original container to protect from light. Store in a dry place. Store below 30°C.

PACKAGING AVAILABLE:

20 kg paper/polyethylene bag.

MANUFACTURER:

BIOVET Joint Stock Company
 39 Petar Rakov Street,
 4550 Peshtera,
 Bulgaria

MARKETING AUTHORIZATION HOLDER:

Pahang Pharmacy Sdn. Bhd. (10826-K)
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 Jalan Meru, 41050 Klang,
 Selangor Darul Ehsan,
 Malaysia

DATE OF REVISION:

March, 2018.