PHARMASIN® 100% W/W Water Soluble Granules (tylosin tartrate)

**COMPOSITION**

<table>
<thead>
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<th>Content</th>
<th>Pharmasin® 100%</th>
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<tbody>
<tr>
<td>Tylosin tartrate</td>
<td>1100 grams contain 1100 grams tylosine tartrate corresponding to 1000 grams tylosin activity, equal to 1000 IU/mg</td>
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**PHARMACOLOGICAL ACTION**

Tylosin is a macrolide antibiotic produced by a strain of *Streptomyces fradiae*. It exerts its antimicrobial effect by inhibiting protein synthesis of susceptible microorganisms. The tylosin spectrum of activity includes Gram-positive bacteria, some Gram-negative strains, such as *Pasteurella*, and *Mycoplasma spp.* 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 metabolised. Most of the residues are excreted in faeces predominantly consisting of tylosin A, tylosin factor D and dihydrodesmycosin.

**INDICATIONS**

The presence of the clinical disease in the herd/flock should be established before preventive treatment is started.

**Pigs:** Treatment and prevention of Porcine Intestinal Adenomatosis (Ileitis) associated with *Lawsonia intracellularis*. Treatment and prevention of Enzootic Pneumonia caused by *Mycoplasma hyopneumoniae* and *Mycoplasma hyorhinis*.

**Calves:** Treatment and prevention of Pneumonia, caused by *Mycoplasma spp.*

**Chickens (Broilers – pullets):** Treatment and prevention of Chronic Respiratory Diseases (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae*. Treatment and prevention of necrotic enteritis caused by *Clostridium perfringens*.

**Turkeys:** Treatment and prevention of infectious sinusitis caused by *Mycoplasma gallisepticum*.

**CONTRAINDICATIONS**

Do not use in animals with known hypersensitivity to tylosin or other macrolides. Do not use in cases with known resistance to tylosin or cross-resistance to other macrolides (MLS-resistance). 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.

**MODE OF ADMINISTRATION**

*Orally,* through the drinking water, milk or milk-replacer. For the preparation of the medicated water/milk/milk-replacer the body weight of the animals to be treated and their actual daily consumption should be taken into account. Consumption may vary depending on factors like age, state of health, breed, husbandry system.
TARGET SPECIES
Pigs, chickens (broilers, pullets), turkeys and calves.

DOSAGE
Oral administration through the drinking water, milk or milk-replacer. 1.1 gram of the veterinary medicinal product corresponds to 1 gram of tylosin. The dosages are as follows:

Calves: 10-20 mg tylosin per kg BW (corresponding to 11-22 mg of the veterinary medicinal product per kg BW), twice daily (= daily dose of 20-40 mg tylosin per kg BW), for 7 to 14 days.

Turkeys: 75-100 mg tylosin per kg BW per day (corresponding to 82.5-110 mg of the veterinary medicinal product per kg BW) for 3-5 days.

Chickens (Broilers, pullets): For the treatment of chronic respiratory disease: 75-100 mg tylosin per kg BW per day (corresponding to 82.5-110 mg of the veterinary medicinal product per kg BW) for 3-5 days. For the treatment of Necrotic Enteritis: 20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product) for 3 days.

Pigs: For the treatment of Enzootic Pneumonia: 20 mg tylosin per kg BW per day (corresponding to 22 mg of the veterinary medicinal product per kg BW) for 10 days. For the treatment of ileitis or PIA: 5-10 mg tylosin per kg BW per day (corresponding to 5.5-11 mg of the veterinary medicinal product per kg BW) for 7 days.

To provide the required amount of active substance in mg per litre drinking water/milk/milk-replacer the following calculation should be made:

\[
\frac{\text{...mg tylosin/kg bodyweight/day}}{\text{Average amount of drinking water / animal (l)}} \times \frac{\text{Average body weight (kg) of the animals to be treated}}{\text{...mg tylosin/l of drinking water}}
\]

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered. After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance which might support development of resistance. Medicated water, milk or milk replacer should be replaced every 24 hours.

If individual animals show signs of a serious infection, such as a reduced water or feed intake, then they should be treated individually, for example by injection.

SIDE EFFECTS
In pigs, adverse reactions have been observed, including diarrhea, pruritus, erythema of the skin, swelling of the vulva, rectal edema and prolapse. These reversible signs appeared 48-72 hours after the start of treatment. There is no evidence of tylosin toxicity in rats, at dose rates of up to 1000 mg/kg by the oral route. There is no evidence of tylosin toxicity in chickens, turkeys, pigs or calves when administered orally at up to three times the recommended dose.
WITHDRAWAL PERIOD
The withdrawal times for EU are:
- Calves (meat and offal): 12 days
- Pigs (meat and offal): 1 day
- Turkeys (meat and offal): 2 days
- Turkey (eggs): Zero days
- Chickens (meat and offal): 1 day
- Chicken (eggs): Zero days
* Please check with your local registration the withdrawal time for your region as this may vary.

STORAGE
Store in the original container in order to protect from light. Do not store above 25°C.

PACKING
Block bottomed zipped 1.1 kg PET-Alu-PE bag.

WARNING
Due to likely variability (time, geographical) in susceptibility of bacteria to Tylosin, bacteriological sampling and susceptibility testing are recommended. Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.

Do not leave or dispose of water containing tylosin tartrate where it may be accessible to animals not under treatment or wildlife. If individual animals show signs of a serious infection, such as reduced water or feed intake, then they should be treated individually, such as by injection.

Because of the possibility of contact dermatitis and irritation of the skin, eyes or respiratory tract, direct contact during administration should be avoided. Macrolides may induce hypersensitivity reactions (allergy) after injection, inhalation, ingestion or contact with the skin. Cross-hypersensitivity to macrolides may be observed. Allergic reactions to these substances may be particularly hazardous. Therefore, direct contact during administering of the product should be avoided. Hypersensitive persons should avoid all contact with the product. Wear a mask, safety glasses and protective gloves when either reconstituting or administering the solution. After preparation of medicated water, wash exposed skin with soap and water. In case of accidental eye contact, wash the eyes thoroughly with water. Contact a physician if a skin rash is observed, in the event of oedema of the face, lips or eyes, or if breathing difficulties are encountered.

Antagonism with substances of the lincosamide group.