PHARMASIN® 2% and 25% Oral granules (tylosin)

COMPOSITION

<table>
<thead>
<tr>
<th>Content</th>
<th>Pharmasin® 2%</th>
<th>Pharmasin® 25%</th>
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</thead>
<tbody>
<tr>
<td>Tylosin phosphate</td>
<td>20 mg</td>
<td>250 mg</td>
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<tr>
<td>Excipients: wheat meal, dipotassium phosphate, pregelatinised starch (potato)</td>
<td>Up to 1 g</td>
<td>Up to 1 g</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 micro-organisms. The tylosin spectrum of activity includes Gram-positive bacteria, some Gram-negative strains such as *Pasteurella*, and *Mycoplasma* spp.

Absorption: tylosin reaches maximal blood levels between 1 and 3 hours after an oral dose.

Distribution: after oral doses were given to pigs, tylosin was found in all tissues between 30 minutes and 2 hours after administration, except for the brain and spinal cord. Compared to plasma levels clearly higher tissue concentrations have been observed.

Metabolism and excretion: most of the material excreted through the faeces consists of tylosin (factor A), relomycine (factor D) and dihydrodesmycosin.

INDICATIONS

**Pigs:** Treatment and prevention of clinical signs of Porcine Proliferative Enteritis (Porcine Intestinal Adenomatosis, Proliferative Hemorrhagic Enteropathy, ileitis) associated with *Lawsonia intracellularis* when the disease has been diagnosed at the group level.

CONTRAINDICATIONS

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

MODE OF ADMINISTRATION

**Orally,** well homogenized into the feed. For use in individual pigs on farms where only a small number of pigs are to receive the medicine. These products are only for administration in small quantities of feed for immediate consumption, to individual animals. Larger groups should be treated with medicated feeding stuff containing the premix.
TARGET SPECIES
Pigs.

DOSAGE
Pharmasin® 2% oral granules: Individual pigs should receive 5 mg tylosin per kg bodyweight, corresponding to 250 mg Pharmasin® 20 mg/g Oral Granules/kg bodyweight, once a day for 3 weeks. This is achieved by thoroughly mixing the product into the daily ration for each individual pig. The required amount of product should be added to the estimated quantity of daily ration for each pig in a bucket or similar receptacle and thoroughly mixed. The product should only be added to dry non-pelleted feed.

Pharmasin® 25% oral granules: Individual pigs should receive 5 mg tylosin per kg bodyweight, corresponding to 20 mg Pharmasin® 250 mg/g Oral Granules/kg bodyweight, once a day for 3 weeks. This is achieved by thoroughly mixing the product into the daily ration for each individual pig. The required amount of product should be added to the estimated quantity of daily ration for each pig in a bucket or similar receptacle and thoroughly mixed. The product should only be added to dry non-pelleted feed. The pig to be treated should be weighed to prevent underdosing. Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered.

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

WITHDRAWAL PERIOD
Pigs (meat): 1 (one) day.

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

PACKING
Pharmasin® is available in 1 and 5 kg packages. Pharmasin® 20 mg/g Oral Granules for pigs are packed in low-density PE/paper bags with sutured crimp, whereas Pharmasin® 250 mg/g Oral Granules 1 kg is packed in a low-density zipper bag.
**WARNING**

Tylosin may induce irritation. Macrolides, such as 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 mixing and handling of the veterinary medicinal product wear 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.