**COMPOSITION**

<table>
<thead>
<tr>
<th>Content</th>
<th>Tilmovet® 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tilmicosin</td>
<td>100 mg</td>
</tr>
<tr>
<td>Excipients: Corn cobs, liquid paraffin, macrogolglycerol ricinoleate, phosphoric acid, concentrated for pH adjustment</td>
<td>Up to 1 g</td>
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**PHARMACOLOGICAL ACTION**

Tilmicosin inhibits the bacterial protein synthesis in vitro and in vivo, without affecting the nucleic acid synthesis. It is mostly bacteriostatic. It has a bactericidal effect on *Pasteurella* spp. Tilmicosin has a wide spectrum of activity against Gram-positive organisms, some Gram-negative micro-organisms (*Pasteurella multocida, Actinobacillus pleuropneumoniae*) and *Mycoplasma* spp. Macrolides inhibit protein synthesis by reversibly binding to the 50S ribosomal subunit. Bacterial growth is inhibited by induction of the separation of peptidyl transfer RNA from the ribosome during the elongation phase. Ribosomal methylase, encoded by the *erm* gene, can precipitate resistance to macrolides by alteration of the ribosomal binding site. The gene that encodes for an efflux mechanism, *mef*, also brings about a moderate degree of resistance. Resistance is also brought about by an efflux pump that actively removes the cells of the macrolide. This efflux pump is chromosomally mediated by genes referred to as *acrAB* genes. Resistance of *Pseudomonas species* and other Gram-negative bacteria, enterococci and staphylococci may be precipitated by chromosomally controlled alteration of permeability or uptake of the drug.

Following oral administration, tilmicosin is distributed throughout the body, but especially high levels are found in the lung and in lung tissue macrophages. It is also distributed in the liver and kidney tissues. Biotransformation: Several metabolites are formed, the predominant one being identified as T1. However the bulk of the tilmicosin is excreted unchanged. Elimination: Following oral administration, tilmicosin is excreted mainly via the bile into the faeces, but a small proportion is excreted via the urine.

**INDICATIONS**

Tilmovet® 100 mg/g Granules is indicated for the treatment of pneumonia in weaned fattening pigs, caused by *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida*, sensitive to tilmicosin.

**CONTRAINDICATIONS**

Do not use in animals hypersensitive to tilmicosin and when there is resistance to tilmicosin or cross-resistance to other macrolides like tylosin, erythromycin or lincomycin. Tilmicosin is known to be toxic for horses. Do not allow horses or other equines access to feeds containing tilmicosin.

**MODE OF ADMINISTRATION**

*Orally*, well homogenized into the feed. The product should be administered to small quantities of feed for immediate consumption by individual animals. For treatment of groups of pigs, use an appropriate premix incorporated...
into medicated feedingstuff by an authorised feed manufacturer. Pigs to be treated should be separated and treated individually. The required quantity of the product should be thoroughly mixed into the daily ration for each individual pig. The feed containing the oral granules should be provided as the sole ration for the periods recommended.

**TARGET SPECIES**
Weaned fattening pigs.

**DOSAGE**
Individual pigs should receive 16 mg tilmicosin per kg body weight, corresponding to 160 mg Tilmovet® 100 mg/g Oral Granules/kg body weight, once a day during 15 days. The pig to be treated should be weighed and the amount of feed that the pig is likely to consume should be estimated. The correct quantity of the 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 nonpelleted feed.

**SIDE EFFECTS**
Occasionally, feed intake may decrease (including feed refusal) in animals receiving medicated feed. This effect is transient. Vomiting and cardio-vascular collapse are symptoms of overdosing.

**WITHDRAWAL PERIOD**
Pigs: meat and offal 21 days.

**STORAGE**
Do not store above 30ºC. Store in the original container in order to protect from moisture.

**PACKING**
Pack of 0.25 kg or 1 kg in a polyethylene-lined 3-ply paper bag. Not all pack sizes may be marketed.

**WARNING**
Cross-resistance between tilmicosin and other macrolide antibiotics have been observed. Accidental ingestion should be avoided by humans. The handling of the product in case of known hypersensitivity to macrolide antibiotics must be avoided. May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Wear overalls, safety glasses and impervious gloves when mixing and handling the product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. In case of accidental ingestion, or if you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention. If the operations involve risk of exposure to dust, wear either a disposable filter and half mask respirator. Do not use simultaneously with other macrolides and lincosamides. Do not mix into feed containing bentonite.