Tylo-Suscit® 100% Kompaktat

1000 mg/g Granules
for pigs, chickens and turkeys

Name and address of the marketing authorisation holder
Bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Name of the veterinary medicinal product
Tylo-Suscit® 100% Kompaktat
1000 mg/g Granules for pigs, chickens and turkeys

Statement of the active substance(s) and other ingredient(s)
1.0 g granules contain:
Pharmacological active substance:

Tylosin tartrate for animals	1000 mg
equivalent to 924 mg tylosin	(924 I.U./mg)

Almost white to slightly yellowish granules.

Indications
Treatment of infectious diseases in pigs, chickens (chicks, laying hens, breeding hens, young hens), turkeys:

Pigs:
- Treatment of enzootic pneumonia, caused by *Mycoplasma hyopneumoniae* and *Mycoplasma hyorhinis*.
- Treatment of Porcine Intestinal Adenomatosis (PIA or Ileitis), caused by *Lawsonia intracellularis*.

Chickens (chicks, laying hens, breeding hens, young hens):
- Treatment of chronic respiratory disease (CRD), caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.
- For metaphylactic treatment of necrotic enteritis (NE), caused by *Clostridium perfringens*, if the disease has been demonstrated in the flock.

Turkeys:
- Treatment of infectious sinusitis, caused by *Mycoplasma gallisepticum*.

Contraindications
- Do not use in animals with known hypersensitivity to tylosin and other macrolide antibiotics.
- Do not use when resistance to tylosin or cross-resistance to other macrolide antibiotics (so called MLS- resistance) is confirmed.
- Do not use simultaneously with a vaccination or vaccination less than one week ago with live vaccines sensitive to tylosin.
- Do not use in animals with liver dysfunction.
- Do not use in horses, because there is a risk of inflammation of the caecum.

Adverse reactions
Reversible, marked redness of the upper skin, especially of the abdominal region and region of the anus, vulva and snout, doughy swellings of the lower abdomen, swelling of the vulva and rectum prolapse are very rarely observed following oral application of tylosin. These changes appeared 48 to 72 hours after starting the treatment. Very rarely abortions in high-bearing sows and cases of death are observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Target species
Pigs, chickens (chicks, laying hens, breeding hens, young hens), turkeys.

Dosage for each species, route(s) and method of administration
1 mg Tylo-Suscit® 100% Kompaktat contains 1 mg tylosin tartrate

Pigs:
For administration via the drinking water.
For treatment of enzootic pneumonia:
22 mg tylosin tartrate/kg body weight (b.w.)/day for a time period of 10 days.
For treatment of PIA and ileitis:
5.5 - 11 mg tylosin tartrate/kg body weight (b.w.)/day for a time period of 7 days.

Chicks:
For administration via the drinking water.
For treatment of *Mycoplasma gallisepticum* infections:
In the 1st week of life, 150 mg tylosin tartrate/kg b.w./day for a time period of 5 to 8 days.
In the 2nd week of life, 100 mg tylosin tartrate/kg b.w./day for a time period of 5 to 8 days.

Chicks, laying hens, breeding hens, young hens:
For administration via the drinking water.
For treatment of chronic respiratory disease (CRD):
82.5 - 110 mg tylosin tartrate/kg b.w./day for a time period of 3 to 5 days.
For metaphylactic treatment of necrotic enteritis (NE):
22 - 44 mg tylosin tartrate/kg b.w./day for a time period of 5 days.

Turkeys:
For administration via the drinking water.
For treatment of infectious sinusitis caused by *Mycoplasma gallisepticum* infections:
82.5 - 110 mg tylosin tartrate/kg b.w./day for a time period of 3 to 5 days.
Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.
The dosage has to be adjusted to the actual, real daily intake of drinking water by the animals as this varies in dependence on the age, state of health, purpose of the animals and the way of rearing (e.g. varying ambient temperature, different light patterns).

For the above mentioned dose, the amount of Tylo-Suscit® 100% Kompaktat to be mixed into the drinking for the animals to be treated is calculated according to the following formula:

$$\frac{\text{... mg Tylo-Suscit 100% Kompaktat per kg b.w./day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal of drinking water}} = \text{... mg Tylo-Suscit® 100% Kompaktat per litre of drinking}$$

Dissolve the needed amount of granules completely and every day fresh in a small part of water and add to the drinking water.
The maximal solubility of Tylo-Suscit® 100% Kompaktat in water is about 133 g/litre.
To ensure the correct dose and to avoid underdosing, the body weight of the animals to be treated should be determined as exactly as possible.
The necessary amount of granules shall be determined by a suitable calibrated scale.
To ensure the intake of the medicated drinking water, the animals should not have access to any other source of drinking water during treatment. If the animals are kept outdoors, they should be kept in the stable during treatment.
The medicated drinking water must be changed every 24 hours.
To ensure an even water uptake by all animals, sufficient watering places have to be provided.
It has to be guaranteed, that the provided dose is taken up completely.
Should there be no significant improvement of the state of health after 3 days of treatment, review diagnosis and change therapy, if necessary.
After conclusion of the treatment, the drinking equipment has to be cleaned thoroughly in a suitable manner to avoid the intake of subtherapeutic, residual amounts of the applied antibiotic supporting resistance formation.
In animals with obviously disturbed state of health, a preparation to be administered parenterally shall be preferred.

Advice on correct administration
See above (method of administration).

Withdrawal period(s)

Chickens (laying hens,	edible tissues:	1 day
breeding hens, young hens):	eggs:	0 days
Chicks:	edible tissues:	2 days
Pigs:	edible tissues:	1 day
Turkeys:	edible tissues:	5 days

Special storage precautions
Keep container tightly closed. Keep out of the reach and sight of children.
Shelf life after first opening the container: 14 days.
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Stability of the medicated drinking water: 24 hours
Do not use after the expiration date stated on the label.

Special warnings

Special warnings for each target species:

Avoid administration of tylosin 3 days prior to and one week after a Newcastle Disease vaccination.
Animals with acute infection may show a reduced food and water intake.
In case of insufficient water intake, treat the animal parenterally.
During treatment, unmedicated drinking water should only be administered after the animals have ingested the daily amount of medicated drinking water.

Special precautions for use:

Special precautions for use in animals:

The application of the product should be based on susceptibility testing of the bacteria isolated from diseased animals of the affected farm.
If this is not possible, the treatment should be based on local (regional, applicable for the respective farm) epidemiological findings on the sensitivity of the target bacteria
In the use of the product, the official national and regional policies on the use of antibiotics must be observed.
An application of the product deviating from the information in the SPC may increase the prevalence of bacteria resistant to tylosin and reduce the effectiveness of treatment with other macrolides due to the potential for cross-resistance.
Water containing tylosin should not be left in or discarded where it is accessible to untreated animals or wildlife. Repeated use should be avoided by improving operational management and hygiene practices.

Special safety precautions to be taken by the person administering the medicinal product to animals:

Tylosin may cause irritation. Persons with known hypersensitivity to macrolids as tylosin shall avoid the contact with the veterinary pharmaceutical product.
During preparation and application of the medicated drinking water, skin contact with the veterinary medicinal product and inhalation of dust particles is to be avoided.
During mixing and handling of the veterinary pharmaceutical product wear impervious gloves, overall and safety goggles and use a single-use half mask respirator conforming to the European standard EN149 or a respirator conforming to the European standard EN140 with a filter according to EN143.
In case of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, rinse eyes with plenty of clean, running water.
Macrolids like tylosin may cause hypersensitivity reactions (allergy) following injection, inhalation, oral intake, or skin or eye contact.
Hypersensitivity to tylosin can lead to cross-reactions with other macrolids and vice versa.
Allergic reactions to these substances can occasionally be severe.
If after contact rash occur, seek medical advice and to refer the leaflet. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms that require urgent medical attention.
Do not smoke, eat or drink during handling the veterinary medicinal product or when preparing the medicated drinking water. Wash hands after use.

Use during pregnancy, lactation or lay:
Laboratory investigations in mice and rats have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The action of tylosin will be antagonized by simultaneous application of lincosamides as these substances use the identical binding site at the ribosomes.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
There are no indications on toxicity of tylosin in rats after oral doses of up to 1000 mg/kg body weight.
There are no indications on toxicity of tylosin in chicken, turkeys, pigs or calves following oral doses of three times the recommended dose.

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

Special precautions for the disposal of unused product or waste materials
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Date on which the package leaflet was last approved:
05.10.2020

Other informations
OP (1 x 110 g)
OP (1 x 275 g)
OP (1 x 550 g)
OP (1 x 1,1 kg)
OP (1 x 5,5 kg)
BP 12 x (1 x 110 g),
BP 12 x (1 x 275 g)
BP 6 x (1 x 550 g)
BP 12 x (1 x 550 g)
BP 6 x (1 x 1,1 kg)
BP 12 x (1 x 1,1 kg)
BP 5 x (1 x 5,5 kg)
BP 10 x (1 x 5,5 kg)

Not all pack sizes may be marketed.

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