



1.3 Product information

1.3.1 Summary of product characteristics

1 Name of the veterinary medicinal product

Tylosin tartrate and sulfadimidine bolus

2 Qualitative and quantitative composition

Each 18g bolus contains 900 mg of Tylosin tartrate and 600mg of Sulfadimidine, for the full list of excipients, see section 6.1.

3 Pharmaceutical form

Yellow bolus.

4. Clinical particulars

4.1 Target species

Poultry, camel, cattle, swine, sheep and goat.

4.2 Indications for use, specifying the target species

Tylosulf is used to treat infections caused by bacteria susceptible to Tylosin and Sulphadimidine, it is also used to treat coccidiosis and taxoplasmosis.

4.3 Contraindications

Do not administer to animals with hypersensitivity to Tylosin and Sulphadimidine.

Do not administer to horses.

Do not administer orally to rodents or rabbits.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Protective gloves should be worn to avoid skin sensitisation, which may occur when crushing the bolus of the product.

Wash hands after use.

Avoid direct contact with skin and eyes. If contact occurs, wash affected area with copious amounts of water. Seek medical advice if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

Administration to horses has been fatal. Allergic reactions have been associated



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with sulphonamides. Skin reactions have been observed in pigs. Tylosin may cause diarrhoea in some animals.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration.

Livestock- 90kg/bolus

Poultry- 30-36kg/bolus

Camels: young- 2 bolus, adult- 4 bolus

Cattle, swine: young- 1 bolus, adult- 2-3 bolus

Sheep and goats- 0.5-1 bolus.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5 Pharmaceutical properties

5.1 Pharmacokinetics

Tylosin can be absorbed from gastrointestinal after oral administration. Tylosin tartrate can be widely distributed after absorption. The concentration in target organ after parenteral administration is twice to third times higher than that of by oral administration. However, the drug cannot enter ventricular CSF by parenteral administration.

The pharmacokinetics of sulfadimidine is similar with sulfadiazine. The extraction of sulfanomides is slow because of its high plasma protein binding rate. The absorption of sulfadimidine is fast and complete, and the extraction is slow. The effective concentration duration is long. The half-time of horse and cow is 10.7-12.9 hours, pig 15.3 hours, ewe 4.7-5.8 hours.

5.2 Pharmacodynamics

Tylosin is a most strong antibiotics in Macrolides to fight against Mycoplasma. It has similar antibacterial spectrum with erythromycin. Sensitive gram-positive bacteria includes Staphylococcus aureus, Streptococcus pneumoniae,



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Streptococcus, Bacillus anthracis, Erysipelomyces listeria, Listeria monocytogenes, Clostridium perfringens, Clostridium anthrax, etc. Sensitive gram-negative bacteria includes Haemophilus, meningococcus, Pasteurella, etc. Sensitive bacteria can develop resistance to this product, Staphylococcus aureus may develop cross-resistance to tylosin and erythromycin.

Sulfadimidine can effectively fight against gram-positive and gram-negative bacteria, such as Streptococcus pyogenes, Salmonella and Klebsiella pneumoniae. The structure of sulfadimidine is similar with Para-aminobenzoic acid, so it can combine with dihydrofolate synthetase, thus prohibit the synthesis of dihydrofolic acid, and prohibit the growth of bacteria. Para-aminobenzoic acid and its degradation (procaine and tetracaine) has antagonism effect with sulfanomides.

6. Pharmaceutical particulars

6.1 List of excipients

Anhydrous sucrose

Dextrin

Corn starch

Magnesium stearate

Talc

Yellow colorant

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4. Special precautions for storage

Store at the temperature below 30°C and protect from light.

6.5 Nature and composition of immediate packaging

The product is supplied in thermoshaped blister packs made of polyvinylchloride (PVC) and aluminium.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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