

# Tilcosin

For Veterinary Use Only

## Injection

### Composition:

Each ml contains

Tilmicosin (USP).....300mg

### Pharmacology:

#### Mechanism of Action:

- Tilmicosin is a macrolide antibiotic. Binds to 50S ribosome and inhibits protein synthesis and exhibits bacteriostatic activity.
- Ribosome is cell organelle which takes part in protein synthesis, having two parts i.e. 50S and 30S.
- Tilmicosin binds to 50S and inhibits translocation of t-RNA here, which is a vital step in protein synthesis 50S is found only in bacterial Ribosomes and not in that of animals. This fact confers selectivity to **Tilcosin injection**.

#### Pharmacokinetics:

- Apparently concentrates in lung tissue. At 3 days post injection, the lung: serum ratio is about 60:1.
- MIC90 3.12 µg/ml for P.haemolytica persist for a minimum 3-4 days after a single injection.
- Similar absorption through oral and parenteral route.

#### Contraindication/Precautions/Reproductive Safety:

- Not to be used in automatically powered syringes or to be given intravenously as fatalities may result.
- Tilmicosin has been shown to be fatal in swine, non-human primates and potentially fatal in horses.
- Safe use in pregnant animals or in animals to be used for breeding purposes has not been demonstrated.

#### Toxicology:

The cardiovascular system is the target of toxicity, and this toxicity may be due to calcium channel blockage. Administration of intravenous calcium chloride should only be considered if there is positive confirmation of exposure to tilmicosin.

In dogs, tilmicosin induced a negative inotropic effect with consequent tachycardia and a reduction in systemic arterial blood pressure and arterial pulse pressure.

The LD50 in Sheep after SC administration is > 150 mg/kg bw. While through IV it was > 7.5 (1/5 died)

Ref: Cochrane & Thomson, 1990

#### Carcinogenicity studies:

Tilmicosin has not been tested in toxicological studies longer than 12 months in duration and hence the carcinogenic potential of this drug has not been directly determined. There are a number of observations which are relevant in assessing the carcinogenicity of tilmicosin:

with tilmicosin have not identified lesions or proliferative changes which could be considered suggestive of potential neoplasia.

- b) Tilmicosin has been tested in a wide range of genotoxicity assays. All results were negative and it was concluded that the compound has no genotoxic activity.
- c) Tilmicosin is a macrolide antibiotic. This class of chemical has been in widespread usage in humans for many years but there is no evidence of carcinogenicity.

#### Indications:

It is indicated for the treatment of bovine respiratory diseases (BRD) and ovine respiratory diseases (ORD) associated with mannheimia (pasteurella) haemolytica.

#### Dosage Form:

Administer the following dose by subcutaneous injection only:

10mg Tilmicosin per kg or 1ml/30kg.

**Swine:** 1ml / 10kg body weight.

#### Precautions:

- Do not inject more than 15ml per injection site.
- Do not use in lambs less than 15kg body weight.
- Store below 25°C in a cool & dry place.
- Do not use in lactating dairy cattle for human consumption.

- a) The results of available toxicological studies



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