PF TILMICOSIN PREMIX 20% W/W POWDER

Composition:
Tilmicosin……......200mg
Exp. Qs……1g

Description
White Colour Powder

Pharmacodynamic
Tilmicosin is a semi-synthetic antibiotic of the macrolide group, and is believed to affect protein synthesis. It has bacteriostatic action but at high concentrations it may be bactericidal. This antibacterial activity is predominantly against Gram-positive microorganism with activity against certain gram-negative ones and Mycoplasma of a bovine, porcine, ovine and avian origin. In particular its activity has been demonstrated against the following micro-organism:
Pigs: Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae.
Scientific evidence suggests that macrolides act synergistically with the host immune system. Macrolides appear to enhance phagocyte killing of bacteria. Tilmicosin has been shown to inhibit *in vitro* the replication of the Porcine Reproductive and Respiratory Syndrome virus in alveolar macrophages in a dose dependent fashion.
Cross resistance between tilmicosin and other macrolides and lincomycin has been observed.

Pharmacokinetic
Absorption: When administered to pigs via the oral route, tilmicosin moves rapidly out of the serum into areas of low pH.
Distribution: Following oral administration, tilmicosin is distributed throughout the body with especially high levels 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 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.

Indication
Pigs: Prevention and treatment of respiratory disease caused by *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida* and other organisms sensitive to tilmicosin.

Route of Administration
Oral

Recommended dose
The uptake of medicated feed depends on the clinical condition of the animals. In order to obtain a correct dosage, the concentration of tilmicosin has to be adjusted accordingly.
Use the following formula:
Kg Premix/tonne feed = Dose rate (mg/kg bodyweight) x bodyweight (kg) / Daily feed intake (kg) x premix strength (g/kg)
Administer in the feed at a dose of 8 to 16 mg/kg body weight/day of tilmicosin (equivalent to 200 to 400 ppm in the feed) for a period of 15 to 21 days.

Indication	Dose of tilmicosin	Duration of treatment	Inclusion rate in feed
Prevention and treatment of respiratory disease	8-16 mg/kg bodyweight /day	15-21 days	1-2 kg PF Tilmicosin Premix 20% W/W Powder/tonne

Contraindication
Horses or other Equidae, must not be allowed access to feeds containing tilmicosin. Horses fed with tilmicosin medicated feeds may present signs of toxicity with lethargy, anorexia, reduction of feed consumption, loose stools, colic, distension of the abdomen and death.
Do not use in case of hypersensitivity to tilmicosin or to any of the excipients

Interaction with other medicinal products
None known.

Pregnancy and lactation
The safety of tilmicosin has not been established in boars used for breeding purposes.

Side effects
In very rare cases, feed intake may decrease (including feed refusal) in animals receiving medicated feed. This effect is transient.

Symptoms and treatment of overdose
No symptoms of overdose have been seen in pigs fed a ration containing levels of tilmicosin up to 80 mg/kg bodyweight (equivalent to 2000 ppm in the feed or ten times the recommended dose) for 15 days.

Storage
Store in a cool dry place (<30^{o}C). Strictly avoid light and heat exposure.

Warning and Precaution
Keep out of reach of children / Jauhi ubat dari kanak-kanak

Special warnings for each target species
Under practical conditions, the management of respiratory disease outbreaks recognises that acutely ill animals are inappetant and require parenteral therapy.

Special precautions for use in animals
Inappropriate use of the product may increase the prevalence of bacteria resistant to tilmicosin and may decrease the effectiveness of treatment with tilmicosin related substances.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Due to the likely variability (time, geographical) in the occurrence of the resistance of bacteria for tilmicosin, bacteriological sampling and susceptibility testing are recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Tilmicosin may induce irritation. Macrolides, such as tilmicosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tilmicosin 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 preparation of the medicated feed, wear overalls, 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. Do not eat, drink or smoke when handling this product. Wash hands after use.
In the case of accidental ingestion, wash out mouth immediately with water and seek medical advice. 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.

Shelf life
36 months

Shelf life after opening
24 hours

Shelf life after dilution or constitution
24 hours

Withdrawal period
Pigs: 21 days

Packaging
25kg

Revised date
27/11/2017

Distributed by:

PANFAST MARKETING (M) SDN.BHD.
PENANG SCIENCE PARK 1102, MUKIM 13, LORONG PERINDUSTRIAN BUKIT MINYAK 18, KAWASAN PERINDUSTRIAN BUKIT MINYAK,
14100 SIMPANG AMPAT, PENANG, MALAYSIA
TEL: +604-5016868 FAX: +604-5016866

Manufactured by:

SHENNONG ANIMAL HEALTH (M) SDN.BHD.
No. 2, 4, 6, 8, 10, Jalan Industri USJ 1/19, Taman Perindustrian USJ 1
47610 SUBANG JAYA, Selangor Darul Ehsan, Malaysia.
Tel: 03-8011 4646 Fax : 03-8024 1166