PACKAGE INSERT

1) Brand or Product Name/ Name and Strength of Active Substance(s)

AVET Chlortetracycline HCL Feed Grade 15% w/w Granular

2) Product Description

Brown to dark brown granular.

3) Pharmacodynamics/Pharmacokinetics

Pharmacodynamics: Chlortetracycline is a natural broad spectrum antibiotic of the tetracycline group. Its activity is bacteriostatic by interfering with the protein synthesis at the S30 ribosome sub-unit.

At recommended dosages, it has no pharmacological effects on cardiovascular, nervous or other body systems.

Pharmacokinetics: When dosed orally it is quickly absorbed into the blood stream. In-feed dosing provides steady to near steady state plasma levels. This provides effective concentrations in various tissues, including lungs and other respiratory tissues.

The major metabolite is 4-epi-chlortetracycline.

4) Environmental Properties

Do not empty into drains. Soluble in water persistence is unlikely based on information available.

5) Indication

For treatment and control of respiratory and systemic infections associated with organisms sensitive to chlortetracycline.

6) Recommended Dosage/ Mode of Administration

The recommended dose rates are as follows:

Pigs: 10–20 mg/kg bodyweight daily Chickens: 20-30 mg/kg bodyweight daily Turkeys: 10-30 mg/kg bodyweight daily Ducks: 10-30 mg/kg bodyweight daily

These dose rates can usually be achieved by mixing 2.0 kg of per tonne of AVET Chlortetracycline HCl Feed Grade 15% w/w Granular per tonne of complete feed to give a concentration of 300 ppm chlortetracycline hydrochloride. However, the correct incorporation rate should always be calculated based on the feed consumption rates of the animals to be treated.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of chlortetracycline has to be adjusted accordingly. To ensure thorough dispersion of the product, it should first be mixed with a suitable quantity of feed ingredients before incorporation into the final mix.

AVET Chlortetracycline HCl Feed Grade 15% w/w Granular can be incorporated in pelleted feed preconditioned at temperatures up to 70°C. The medicated feed should be supplied to the affected pen(s) or group(s) of pigs, chickens, turkeys or ducks. Treatment should be continued for a period of five to seven days for respiratory or systemic infections. During the treatment period, only feed medicated with the product should be supplied.

For incorporation into dry feed at the registered mill. A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or pre-mixtures containing such products must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

7) Contraindications

Do not use in ruminants.

8) Warnings and Precautions

Special warnings

None

Special precautions for use

i. Special precautions for use in animals $% \label{eq:continuous} % \label{e$

Official, national and regional antimicrobial policies should be taken into account when the product is used.

ii.Special precautions to be taken by the person administering the veterinary medicinal

AVET CHLORTETRACYCLINE HCI FEED GRADE 15% w/w GRANULAR

product to animals.

If you know you are hypersensitive (allergic) to chlortetracycline, do not handle the product. When handling this product, inhalation of the dust must be avoided by wearing a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

Avoid contact with skin and eyes. Gloves should be worn whilst handling this product. If contact with skin or eyes occurs, wash area immediately with clean fresh water. If irritation persists, seek medical attention.

Do not eat, drink or smoke whilst handling the product. Hands and exposed skin should be washed thoroughly after use.

9) Interactions with Other Medicaments

Chlortetracycline is sometimes used in association with other antimicrobials, notably sulphadimidine, penicillin and neomycin. There are no known adverse reactions with these or any other substances.

10) Statement on usage during pregnancy and lactation

No problems known.

11) Adverse Effects/Undesirable Effects

The product is of low toxicity and side effects are rarely encountered. If suspected adverse reactions occur, treatment should be discontinued immediately.

12) Overdose and Treatment

Chlortetracycline is of low toxicity and there is a wide safety margin at the recommended dosage. On rare occasions overdosage may cause diarrhea and over growth of yeast and fungi. Under such conditions, withdraw medication and apply appropriate treatment. Please stop medication immediately and seek for veterinarian consultation if there is a sign of overdosage.

13) Withdrawal Period(s)

Meat: Animals must not be slaughtered for human consumption during

treatment.

Ducks

Pigs 10 days Chickens 2 days Turkeys 2 days

Eggs: Chickens and Turkeys - Eggs of treated animals should not be used for

human consumption.

4 days

14) Storage Condition

Store in dry place below 30 °C, protect from light.

15) Dosage Forms and packaging available

25 kg

16) Name and Address of manufacturer

Pucheng Chia Tai Biochemistry Co.,Ltd

No. 56 Dashixi, Putan Village, Pucheng, Fujian, China.

17) Marketing authorization holder / Distributed by:

Asia Veterinary Sdn. Bhd.

2255, Mk 14, Jalan Persekutuan, Bukit Minyak, 14000 Bukit Mertajam, Penang. Tel: +604 502 8888

18) Maximum Residual Limit (MRL)

10) Maximum Residual Limit (MIL)				
	Substance	Residues	Food	MRL in food μg/kg
	Tetracycline	Sum of parent drug	Muscle (cattle, poultry, pig and sheep), milk (cattle)	100
		and its 4-	Egg (poultry)	200
		epimer	Liver (cattle, poultry, pig and sheep)	300
			Kidney (cattle, poultry, pig and sheep)	600

19) Shelf life: 2 years

Date of Revision of Package Insert: 02/10/2021