YH Salinomycin 12% W/W Granule

ACTIVE CONSTITUENT: Salinomycin Sodium 120mg/g

PRODUCT DESCRIPTION: Brown to yellowish-brown granule. **ROUTE OF ADMINISTRATION:** Oral administration.

INDICATIONS: YH Salinomycin 12% W/W Granule is used for control of coccidiosis caused by *Eimeria Acervulina*, *E. brunetti*, *E. maxima*, *E. necatrix*, *E. tenella* in broilers and replacement chickens intended for used as caged layers.

RECOMMENDED DOSE: Broiler Chicken & Caged Layers: Thoroughly mix 500 grams of YH Salinomycin 12% W/W Granule to each 1 tonne of chicken feed. This produces a Salinomycin sodium level of 60 g/tonne in the finished feed which should be fed continuously as the sole ration.

PHARMACODYNAMICS: Salinomycin, like other polyether ionophores, is effective against sporozoites as well as early and late asexual stages of coccidia in the intestines of chickens. The biological activity is based on the ability of ionophores to form lipid soluble and dynamically reversible complexes with ions (preferably the alkaline ions K+ and Na+). Salinomycin encloses the cation in a hollow ball, in the centre of which the cation is fixed and immobilised. It functions as a carrier of ions, mediating an electrically-neutral exchange of cations across the membranes. The resultant changes in transmembrane ion gradients and electrical potentials often produce profound effects on cellular function and metabolism that can lead to the death of coccidia.

PHARMACOKINETIC: The active ingredient is absorbed quickly and well. Salinomycin is rapidly distributed and eliminated. The serum concentration kinetics most closely correspond to a two-compartment model with a distribution phase that ends after one hour. Since the active ingredient is lipophilic and can easily diffuse through cell membranes, the distribution of salinomycin in tissue is greater than in serum. The highest concentrations are found in liver, followed by the kidneys, muscles, fat, heart and skin. The active ingredient can no longer be detected in the tissue after 48 hours, except in the liver where traces can be measured up to 72 hours after application.

WARNINGS AND PRECAUTIONS: Do not exceed recommended use levels. This product should not be fed to horses or any other animal not included in the label claim. Salinomycin can cause cardiac and muscular paralysis and conduction defects some species such as horses and dogs.

INTERACTION WITH OTHER MEDICINAL PRODUCT: This product must not be fed to animals receiving Tiamulin. Care must be excercised when feeding concurrently with other antimicrobials. Tiamulin inhibits biotransformation in the liver, thus stopping detoxication. Other drugs especially antibiotics such as erythromycin and tylosin (macrolide) and lincomycin have this property. Delaying elimination of salinomycin may necessitate a withholding period.

PREGNANCY AND LACTION: Do not use in animals producing milk for human consumption. Do not use in birds during lay, where eggs or egg products are to be used for human consumption or processing. Do not use in birds within 7 days of laying where eggs and egg products are to be used for human consumption. If laying takes place within 7 days, the eggs and egg products must not be used for human consumption or processing.

SYMPTOMS AND TREATMENT OF OVERDOSE: After 5 weeks 120 mg salinomycin sodium from YH Salinomycin 12% W/W Granule kg⁻¹ feed had no negative effect on performance, clinical, metabolic and histological health status of the chickens. But already at 140 mg salinomycin sodium per kg feed performance in terms of final weight, weight development and feed intake was negatively affected and disturbance of serum calcium level and haemoglobin values were observed. Beginning with 160 mg salinomycin sodium per kg a reduction of the production index is observed, and creatinine levels, the alkaline phosphatase activity and cholinesterase values in plasma became affected. On a 3-fold overdose (180 mg salinomycin sodium kg-1 feed) also feed conversion was disturbed and health status affected in terms of feed intake and clinical appearance. In addition serum sodium level and mean corpuscular volume were reduced.

STORAGE CONDITION: Store below 30°C in a cool dry place. Protect from light. Keep container tightly closed. **CONTRAINDICATION:** This product should not be fed to horses or any other animal not included in the label claim. Salinomycin

can cause cardiac and muscular paralysis and conduction defects some species such as horses and dogs. It is recommended that the appropriate amount of premix be extended with at least 9.5 kilos of ground meal which is then added gradually to the feed blend.

SIDE EFFECTS: None known.

WITHDRAWAL PERIOD:

Meat: Poultry: Zero (0) days

Eggs: Do not use in birds during lay, where eggs or egg products may be used for human consumption.

Do not use in birds within 7 days of lay where eggs may be used for human consumption. If laying takes place within 7 days, the eggs, egg products must not be used for human consumption.

SHELF LIFE AFTER FIRST OPENING OF CONTAINER: 7 days at not above 30°C. SHELF LIFE AFTER RECONSTITUTOIN OR DILUTION: 3 months at not above 30°C.

DATE OF REVISION: March 2024 SHELF LIFE: 2 years PACKAGING: 25kg/bag.

PRODUCT REGISTRATION NUMBER:

CONTROLLED MEDICINE/ "UBAT TERKAWAL"

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN/ "JAUHI UBAT DARI KANAK-KANAK"

MANUFACTURED BY:

Shandong Qilu King-Phar Pharmaceutical Co., Ltd. Add: No.21 Qinglong Road, Pingyin, Jinan, China.

PRODUCT REGISTRATION HOLDER:

Yenher Agro-Products Sdn.Bhd.,

Add.: 1628, Jalan IKS Simpang Ampat1. Taman IKS Simpang Ampat, 14100 Simpang Ampat. Seberang Perai Selatan, Penang, Malaysia.