

PRODUCT LITERATURE

PRODUCT NAME : DOXYLE 50% w/w WSP

Each One Gram Contains:

Active Ingredient:

Doxycycline hyclate 500 mg

Product Description:

Yellow, odourless powder

Target Species:

Non-egg laying chickens.

Route of Administration

Orally

Pharmacodynamics:

Doxycycline is a broad spectrum antibiotic. It inhibits the intracellular bacterial protein synthesis by binding on the 30S ribosomal subunits. As such, the access of aminoacyl-tRNA to the receptor location of the mRNA-ribosomal complex is blocked. As a result the linkage of amino acids to the forming peptide chain is inhibited. Doxycycline inhibits bacteria, Mycoplasmas, Chlamydia, Rickettsia, and certain Protozoa.

Four resistance mechanisms acquired by microorganisms against tetracyclines in general have been reported: decreased accumulation of tetracyclines (decreased permeability of the bacterial cell wall and active efflux), protein protection of the bacterial ribosome, enzymatic inactivation of the antibiotic and rRNA mutations (preventing the tetracycline binding to ribosome). Tetracycline resistance is usually acquired by means of plasmids or other mobile elements (e.g. conjugative transposons). Cross resistance between tetracyclines has also been described. Due to the greater lipo solubility and greater facility to pass through cell membranes (in comparison to tetracycline), doxycycline retains a certain degree of efficacy against microorganisms with acquired resistance to tetracyclines.

Pharmacokinetics:

Doxycycline is rapidly and almost fully absorbed from the intestine. Presence of food in the intestine has no influence on the absorption of doxycycline. The distribution of doxycycline throughout the body and the penetration in most tissues is good. Tetracyclines are virtually not metabolised after absorption. In contrast to other tetracyclines, doxycycline is primarily excreted via the faeces. Steady state plasma concentrations of 2.05 ± 0.47 µg/ml were reached within 6 hours after start of the medication and varied between 1.28 and 2.18 µg/ml with a dosage of 25 mg/kg body weight during 5 days

Indication:

Treatment of the following specified infections of the respiratory tract and alimentary tract caused by micro-organisms susceptible to doxycycline. Non-egg laying chickens: Infections of the respiratory tract

caused by Mycoplasma spp, Escherichia coli, Avibacterium paragallinarum and Bordetella avium. Enteritis caused by Clostridium perfringens and Clostridium colinum.

Recommended Dose:

Non-egg laying chicken: 25 mg doxycycline hyclate per kg bodyweight per day, corresponding to 50 mg of product per kg bodyweight, per day for 3-5 days. Route of administration: For the administration through the drinking water, the exact daily amount of product should be calculated, based on the recommended dose, and the number and weight of the birds to be treated, according to the following formula:

$$\text{Mg product per litre drinking water} = \frac{\text{Mg product/kg bodyweight/day} \times \text{mean bodyweight (kg) of birds to be treated}}{\text{Mean daily water consumption (litre) per animal}}$$

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical conditions of the birds and the concentration of doxycycline should be adjusted accordingly. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated presolution – approximately 100 grams product per litre drinking water – and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator. Medicated water should be the only drinking source.

Use appropriately and properly calibrated dosing equipment.

Contraindications:

Do not use in cases of hypersensitivity to tetracyclines or any of the excipients. Do not administer to animals with severe liver or kidney insufficiency.

Warning & Precautions:

Special warnings for each target species
None.

Special precautions for use

Special precautions for use in animals

Due to variability (time, geographical) in susceptibility of bacteria to doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased animals on farm are highly recommended. A high resistance rate of E.coli isolated from chickens, against tetracyclines has been documented. Therefore the product should be used for the treatment of infections caused by E.coli only after susceptibility testing has been carried out. As eradication of the target pathogen may not be achieved, medication should therefore be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

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

This product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with the skin or eyes (powder and solution), or if the powder is inhaled. People with known hypersensitivity to

tetracyclines should not handle the product. Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. a disposable half-mask respirator conforming to European Standard EN 149 (FFP2) or a non-disposable respirator to European Standard EN 140 with a filter to EN 143) when applying the product.

Do not smoke, eat or drink while handling the product. In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention. Wash hands and contaminated skin immediately after handling the product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Interactions With Other Medicaments:

Do not administer in combination with bactericidal antibiotics, such as penicillins and cephalosporins. Doxycycline absorption may be reduced by the presence of high quantities of calcium, iron, magnesium or aluminium in the diet.

Pregnancy & Lactation:

Laying birds: Do not use in birds in lay and within 4 weeks before the start of the laying period.

Side Effects:

None known.

Symptoms and Treatment of Overdose

Doxycycline has a high therapeutic index. The normal dose for oral use is 25 mg/kg bodyweight, where the LD50 for the most sensitive animal species is 1700 mg/kg bodyweight after oral administration.

Withdrawal period

Meat and Offal: 5 days. Not for use in birds producing or intended to produce eggs for human consumption.

Maximum Residual Limit

Muscle (poultry) 100

Liver (poultry), fat (poultry) 300

Kidney (poultry) 600

Disposal Of Container

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

Storage Condition

To be stored below 30 degree, protected from light

Shelf Life as packaged for Sale

2 years from the date of manufacturing

Shelf Life after first opening of container

To be used 24 hours after first opening

Shelf life after reconstitution or dilution

To be used 24 hours after dilution

Packing Size: Aluminum Pouch of 500gm and 1kg.

Product Registration Holder By:

GNC AGRITECH SDN BHD

24 Jalan Industri CheroK Tokun3, Taman Tokun Jaya,

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Manufactured By:

Dexchem Industries Sdn. Bhd.

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