

For Veterinary Use Only

Peradoks[®]

50% Powder for Oral Solution

Veterinary Antibacterial

COMPOSITION:

A yellowish coloured, fluent, water-soluble powder which contains doxycycline hyclate, (hydrochloride) equivalent to 500mg Doxycycline, per each g.

PHARMACOLOGICAL PROPERTIES:

The active substance of Peradoks 50% Powder for Oral Solution, doxycycline, is a semi-synthetic tetracycline derivative. Generally, tetracycline group antibiotics are very effective against Gram-positive aerobes (*Bacillus* sp., *Corynebacterium* sp., *Erysipelothrix rhusiopathia*, *Listeria monocytogenes* and *Streptococci*.); Gram-negative bacteria (*Actinobacillus* sp., *Bordetella* sp., *Francisella tularensis*, *Haemophilus* sp., *Pasteurella multocida*, *P. haemolytica*, *Yersinia* sp., *Campylobacter fetus*, *Borrelia* sp. *Leptospira* sp. and *Moraxella bovis*); anaerobes (*Actinomyces* sp., *Fusobacterium* sp.,) and *Mycoplasma* sp., *Chlamydia* sp., *Ehrlichia* sp., *Coxiella burnetii*, *Ehrlichia*, *Theileria*, *Eperythrozoon* and *Anaplasma*.

Its activity over *Staphylococci*, *Enterococci*, *Enterobacter* sp., *Enterobacter* sp. of *Enterobacteriaceae*, *E.coli*, *Klebsiella* sp., *Proteus* sp., *Salmonella* sp. and Anaerobe bacteria such as *Bacteroides* sp. and *Clostridium* sp. is various due to gained resistance.

It is considered as resistant to *Mycobacterium* sp., *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Serratia* sp., *Mycoplasma bovis* and *M. hyopneumoniae* tetracyclines.

The mechanism of effect is based on the inhibition of protein synthesis by irreversibly binding to 30 S subunits of bacterial ribosomes. It has a bacteriostatic effect. Doxycycline, in comparison with other tetracycline antibiotics, is more lipophilic; highly lipid-soluble; and binds to proteins at high ratios (90%) and has a long half life (15-22 hours). When administered orally to chicken at a dose of 10mg/kg live weight it is rapidly and well absorbed. The peak concentration is 4.47 + / - 0.16 microgram/ml and it reaches peak concentration (C_{max}) within 1.73 + /0.06 hours. Elimination half life in winged animals and calf is 4.6 hours and 9.8 hours, respectively. Oral bioavailability has been reported as 41-73.4%. Doxycycline is metabolized and mainly excreted through stools as inactive metabolites.

AREA OF USE / INDICATIONS:

Peradoks 50% Powder for Oral Solution is used for the treatment and control of bacterial infections in calf, broiler chicken and turkeys.

In cattle; bacteria origin diarrhoea, colisepticaemia, bronchopneumonia, polyarthritis, calf diphtheria and infections of umbilical cord;

In broiler chicken and turkeys; bacteria origin diarrhoea, colisepticemia, CRD complex, air sac infections, salpingitis, cholera, coryza and staphylococcus infections.

USAGE AND DOSAGE:

Peradoks 50% Powder for Oral Solution is added into drinking water for administration to broiler chicken and turkeys at a dose of 20mg/kg live weight. Unless otherwise recommended by the Veterinary Surgeon, 400g

Peradoks Powder for Oral Solution is added into the required drinking water amount for 10 ton C.A. (approximately 1000L). Treatment duration is 5 days.

The dose for calf is 1g for 50 kg C.A. The proper drug amount is added into quarter litre (2 tea glasses) of drinking water or milk. Daily dose should be divided into two and administered at intervals of 12 hours for calf. Drug administration should be continued for 3-5 days by considering the course of infection.

UNDESIRE/SIDE EFFECTS

When used at high doses for a long time, it may cause fatty hepatic degeneration in pregnant animals and the ones with previous hepatic failure; and yellowing and graying of teeth and bones in young animals. Tetracyclines may cause photosensitization and allergic reactions. LD50 is 2500mg/kg in winged animals.

DRUG INTERACTIONS:

Tetracycline group antibiotics should not be used in combination with beta-lactam and aminoglycoside antibiotics. They enhance the nephrotoxic effect of methoxyflurane. It is pharmaceutically incompatible with ampicillin sulphate, aminophylline, amphotericin B, amobarbital sodium, dimenhydrinate, iron dextran, erythromycin gluceptate, fenobarbital sodium, hydrocortisone sodium succinate, calcium chloride, calcium gluconate, carbenicillin disodium, chloramphenicol sodium succinate, meperidine hydrochloride, methicillin sodium, methohexital sodium, morphine sulfate, oxacillin sodium, penicillin G sodium, penicillin G potassium, pentobarbital sodium, cephalothin sodium, cephapirin sodium, sodium bicarbonate, thiopental sodium, warfarin sodium.

All tetracycline group antibiotics create chelation with double ions as calcium magnesium. Therefore, addition of the drug into calcium-rich milk or feed reduces the bioavailability of the drug.

SYMPTOMS OF OVERDOSE AND ANTIDOTE:

Administration of tetracycline at high doses may lead to liver damage. Affected animals may develop hepatitis, acidosis and shock. As doxycycline is eliminated through bile duct at normal doses, dose reduction is not required in cases of renal failure. However, in case of renal failure, when it is used at high doses acidosis, increase in plasma nitrogen and phosphate level and serious disorders of electrolyte balance may be observed.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): is 4 days for broiler chickens and 6 days for turkeys. Calf should not be sent for slaughtering for 14 days following final drug administration. Avoid using in winged animals whose eggs are presented to human consumption.

CONTRAINDICATIONS:

Avoid using in animals whose rumen activity has started. Avoid administering to cats, dogs and horses.

It should not be used for animals sensitive to tetracycline and who have liver and kidney failure.

Use during pregnancy: Due to their side effects, tetracyclines should not be used during the first and last 1/3 of pregnancy.

GENERAL WARNINGS:

Consult your veterinary surgeon before using and in case an undesired effect is observed. Keep out of reach of children. Use only for target species. Do not purchase expired, opened, torn and burst packages.

SPECIAL WARNINGS FOR APPLIER AND VETERINARY SURGEON:

When administered with bivalent or trivalent metals such as calcium, magnesium, iron and aluminium; and kaolin, antacids and bismuth subsalicylate; the absorption of tetracycline antibiotics is reduced. Despite doxycycline binds calcium less than other tetracyclines do, it binds iron more. Avoid using together with these types of substances.

STORAGE CONDITIONS AND SHELF LIFE:

The product should be stored at room temperature (15 – 25 oC) and should be protected from light. Shelf life is 2 years (24 months).

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:

The drug whose shelf life is expired and that is kept for a long time without complying with storage conditions should be disposed together with inner package (bottle).

COMMERCIAL PRESENTATION FORM :

Offered for market in 20g (20 pieces) and 100 g (10 pieces) aluminium folio bags in cardboard boxes; and in 500 g, 1000 g and 5 kg HDPE jar packages without boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 03.04.06

MARKETING AUTHORIZATION DATE AND NO: 13.12.2005-15/039

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Saęlık Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

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