Only for Veterinary Use

Peradoks®

25% Oral Solution

Veterinary Antibacterial

COMPOSITION

It is yellow – dark yellow and viscous solution which contains doxycycline hyclate equivalenet to 250 mg doxycycline per ml.

PHARMACOLOGICAL PROPERTIES

Active substance of Peradoks 15 % oral solution, doxycycline, is a semi-synthetic tetracycline derivative. In general, tetracycline antibiotics have good effects on gram-positive aerobes (Bacillus sp., Corynebacterium sp., Erysipelothrix rhusiopathia, Listeria monocytogenes ve Streptococci), Gram-negative bacteria (Actinobacillus sp., Bordetella sp., Francisella tularensis, Haemophilus sp., Pasteurella multocida, P. haemolytica, Yersinia sp., Campylobacter fetus, Borrelia sp., Leptospira sp.. Moraxella bovis), anaerobic bacteria (Actinomyces sp., Fusobacterium sp.,) Mycoplasma sp., Chlamydia sp., Ehrlichia sp., Coxiella burnetti, Ehrlichia, Theileria, Eperythrozoon and Anaplasma.

Effect on Staphylococci, Enterococci, Enterobacter sp., Enterobacter sp., in Enterobacteriaceae, E.coli, Klebsiella sp., Proteus sp., Salmonella sp. as well as anaerobic bacteria including Bacteroides sp. and Clostridium sp. is variable due to acquired resistance.

Mycobacterium sp., Proteus vulgaris, Pseudomonas aeroginosa, Serratia sp., Mycoplasma bovis ve M. hyopneumoniae are regarded as resistant to tetracycline.

Effect mechanism is based on the inhibition of protein synthesis by binding to 30-50 S sub-unit of bacterial ribosomes. It has bacteriostatic effects. In comparison with other tetracyclines, doxycycline is more lipophilic and it has good lipid solubility; it is bound to proteins at high rate (90%) and elimination half time is long (15-22 hours). Absorption is good and rapid when it is orally administered to chicks at dose of 10 mg/kg live body weight. Peak plasma concentration is 4.47 +/- 0.16 µg/mL and time to peak concentration, Cmax, is 1.73 +/- 0.06 hours. Elimination half time is 4.6 hours in poultry and 9.8 in calf. Oral bio-availability is reported as 41-73.4 percent. Doxycycline is metabolized and it is primarily excreted in form of inactive metabolites via faeces.

AREA OF USE/INDICATIONS

Peradoks 25 % Oral Solution is used in slaughter chick and turkeys for treating bacterial diarrhea, colisepticemia, CRD complex, ORT, air sac infections, salpingitis, cholera, coryza and Staphylococcus infections.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Peradoks is added to drinking water of slaughter chick and turkey at dose of 10-20 mg/kg live body weight. Unless otherwise advised by veterinary surgeon, 1L Peradoks 25% oral solution is added to fresh drinking water for 12500 – 25000 kg live body weight. Treatment period is 5 days.

ADVERSE / SIDE EFFECTS

Tetracyclines may lead to photosensitization and allergic reactions. LD50 is 2500 mg/kg in poultry.

DRUG INTERACTIONS

Tetracycline antibiotics should not be concomitantly used with beta-lactam and aminoglycoside antibiotics. They potentiate nephrotoxic effect of methoxyfluorane. It is pharmaceutically incompatible with amikasin sulphate, aminophylline, amphotericin B, amobarbital sodium, dimenhydrinate, iron dextran, erythromycin gluceptate, phenobarbital sodium, hydrocortisone sodium succinate, calcium chloride, calcium gluconate, carbenicillin disodium, chloramphenicol sodium succinate, meperidine hydrochloride, methicillin sodium, methohexital sodium, morphine sulphate, oxacillin sodium, penicillin G sodium, penicillin G potassium, pentobarbital sodium, cephalotin sodium, cephapirin sodium, sodium bicarbonate, thiopental sodium and warfarin sodium.

All tetracycline antibiotics form chelates with ions with two charges such as calcium and magnesium. Therefore, administrations made in milk or formula rich in calcium may decrease bioavailability of the drug.

SIGNS OF OVERDOSE AND ANTIDOTE

High dose tetracycline may lead to hepatic damage. Icterus, uremia, acidosis and shock may occur in involved subjects. Dose reduction is not required in renal failure cases since doxycycline is usually eliminated via bile ducts at normal therapeutic doses. However, when it is administered at high doses in case of renal failure, following signs and symptoms can be observed: acidosis, elevated plasma nitrogen and phosphate levels and severe electrolyte balance disorders.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP) is 4 days for broilers and 6 days for turkeys. Eggs of treated turkey and poultry should not be offered to consumption by human.

CONTRAINDICATIONS

It should not be used in animals sensitive to tetracyclines as well as animals with hepatic and renal insufficiency.

GENERAL WARNINGS

Please refer to the veterinary surgeon before use and in case of an unexpected effect. Keep out of reach of the children. It should be administered only to target species.

SPECIAL WARNINGS TO TREATING VETERINARY SURGEON

Absorption reduces if tetracyclines are concomitantly used with bivalent or trivalent metals such as calcium, magnesium, iron and magnesium as well as antacids and bismuth subsalicylate. Doxycycline is poorly bound to calcium in comparison with other tetracyclines, while it is better bound to iron. It should not be used concomitantly with those substances.

STORAGE CONDITIONS AND SHELF LIFE

Store at room temperature (15-25ºC) away from exposure to light. Shelf life is 2 years (24 months).

END-OF-USE DISPOSAL AND WARNING FOR THE NON-TARGETED SPECIES

Expired drug or the drug which had been stored without complying to storing conditions should be disposed in original interior packaging (bottle).

FORM OF COMMERCIAL SUPPLY

It is supplied in 500 ml, 1 L, 2.5 L and 5L white high-density polyethylene packaging.

SALE PLACE AND CONDITIONS

It is sold in the veterinary offices and the pharmacies with prescription written by veterinary surgeon (VP).

PACKAGE INSERT VALIDATION DATE: 29.11.2011

LICENSE DATE AND NO: 22.11.2011-25/012

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

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NAME AND ADDRESS OF MANUFACTURER COMPANY:

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