

OTC-20 PREMIX POWDER

Ingredient(s):

Each g contains :

Oxytetracycline (as Hydrochloride)..... 200mg

Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics):**Pharmacodynamics:**

Oxytetracyclines generally act as bacteriostatic antibiotic and inhibit protein synthesis by reversibly binding to 30S ribosomal subunits of susceptible organism, thereby preventing binding to those ribosomes of aminoacyl transfer-RNA. Tetracyclines also are believed to reversibly bind to 50S ribosomes and additionally alter cytoplasmic membrane permeability in susceptible organisms. In high concentrations, tetracyclines can also inhibit protein synthesis by mammalian cells.

Both oxytetracycline and tetracycline are readily absorbed after oral administration to fasting animals. Bioavailabilities are approximately 60~80%. The presence of food or dairy products can significantly reduce the amount of tetracycline absorbed, with reductions of 50% or more possible. Tetracyclines are widely distributed in the body, including to the heart, kidney, lungs, muscle, pleural fluid, bronchial secretions, sputum, bile, saliva, urine, synovial fluid, ascitic fluid, and aqueous and vitreous humor. Only small quantities of tetracycline and oxytetracycline are distributed to the CSF and therapeutic levels may not be attainable. All tetracyclines distribute to the prostate and eye. The volume of distribution of oxytetracycline is approximately 2.1L/kg in small animals, 1.4L/kg in horses, and 0.8L/kg in cattle. The amount of plasma protein binding is about 10~40% for oxytetracycline.

Pharmacokinetics:

Both oxytetracycline and tetracycline are eliminated unchanged primarily via glomerular filtration. Patients with impaired renal function can have prolonged elimination half-lives and may accumulate the drug with repeated dosing. These drugs apparently are not metabolized, but are excreted into the GI tract via both biliary and nonbiliary routes and may become inactive after chelation with fecal materials. The elimination half-life of oxytetracycline is approximately 4~6 hours in dogs and cats, 4.3~9.7 hours in cattle, 10.5 hours in horses, 6.7 hours in swine, and 3.6 hours in sheep.

Indication(s):

Swine:

1. As an aid in the prevention and treatment of bacterial enteritis.
2. As an aid in maintaining weight gains in the presence of atrophic rhinitis.
3. As an aid in stimulating appetite and maintaining weight gains during periods of stress caused by moving, vaccination, castration or extreme temperature changes.
4. As an aid in reducing the incidence of abortion caused by leptospirosis.

Cattle:

1. As an aid in reducing the incidence of bloat in young cattle on pasture and in feed lots.
2. As an aid in the prevention of bacterial enteritis in calves.

Lambs:

1. As an aid in the reduction of bacterial enteritis in creep-fed suckling lambs.
2. As an aid in the reduction of losses due to enterotoxemia (overeating) in feed lot lambs.

Turkeys and/or chickens:

1. As an aid in stimulating appetite and maintaining weight gains or egg production, hatchability, eggshell quality and feed efficiency in the presence of CRD and non-specific enteritis, and while under stress caused by moving, debeaking, vaccination or extreme temperature changes.
2. As an aid in the prevention and treatment of infectious sinusitis and synovitis of turkeys.

Target Species:

Chickens, turkeys, swine, cattle and lambs.

Dosage and Administration:

Swine	As an aid in the prevention of bacterial enteritis.	Mix 1.00kg into every ton of feed continuously until 6 weeks of age.
	As an aid in the treatment of bacterial enteritis.	Mix 1.00kg into every ton of feed following the appearance of symptoms and until 3 days after symptoms disappear- for pigs up to 6 weeks of age.
	As an aid in maintaining weight gains in the presence of atrophic rhinitis.	Mix 0.25kg into every ton of feed continuously.
	As an aid in stimulating appetite and maintaining weight gains during periods of stress caused by moving, vaccination, castration or extreme temperature changes.	Mix 0.50kg into every ton of feed continuously until 10 days after the stress conditions have been eliminated.
	As an aid in reducing the incidence of abortion caused by leptospirosis.	Mix 2.55kg into every ton of sow feed continuously for 2 weeks.
Cattle	As an aid in reducing the incidence of bloat in young cattle on pasture and in feed lots.	Mix 0.25kg into every ton of feed continuously.
	As an aid in the prevention of bacterial enteritis in calves.	Mix 0.25kg into every ton of feed continuously during early growth period.
Lambs	As an aid in the reduction of bacterial enteritis in creep-fed suckling lambs.	Mix 0.50kg into every ton of creep feed continuously during the suckling period.
	As an aid in the reduction of losses due to enterotoxemia (overeating) in feed lot lambs.	Mix 0.10kg into every ton of feed continuously.
Turkeys and/or chickens	As an aid in stimulating appetite and maintaining weight gains or egg production, hatchability, eggshell quality and feed efficiency in the presence of CRD, and while under stress caused by moving, debeaking, vaccination or extreme temperature changes.	Mix 1.00 kg into every ton of feed continuously from the onset of the disease for at least 1 month or until a few days after the symptoms disappeared.
	As an aid in stimulating appetite and maintaining weight gains in the presence of non-specific enteritis.	Mix 0.50kg into every ton of feed continuously from the onset of the disease for at least 1 month or until a few days after the symptoms disappear.
	As an aid in the prevention of infectious sinusitis and synovitis of turkeys.	Mix 0.50kg into every ton of feed continuously.
	As an aid in the treatment of infectious synovitis of turkeys.	Mix 1.00kg into every ton of feed continuously until at least 2 weeks after symptoms disappear.

Orally via feed mixing.

Contraindications:

Contraindicated in patients hypersensitive to it or other tetracycline.

Precaution(s) / Warning(s):

1. In patients with renal insufficiency or hepatic impairment, oxytetracycline and tetracycline must be used cautiously. Lower than normal dosages are recommended with enhanced monitoring of renal and hepatic function. Avoid concurrent administration of other nephrotoxic or hepatotoxic drugs if tetracyclines are administered to these patients.

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Size 260mmx110mm

2. Long term use of this product may lead to development of bacterial resistance and is not recommended. However, the recommended course of treatment should be completed.
3. If you know you are allergic to oxytetracycline, do not handle the product. When incorporating into feed, care should be taken not to inhale any dust when handling the product and skin contact should be avoided. It is recommended that a face mask, be worn during the dispensing of the product. Hands and exposed skin should be washed thoroughly at the end of the operation.

Interaction with Other Medicaments:

- 1) When orally administered, tetracyclines can chelate divalent or trivalent cations, which can decrease the absorption of the tetracycline or the other drug if it contains these cations. Oral antacids, saline cathartics or other GI products containing aluminum, calcium, magnesium, zinc or bismuth cations are most commonly associated with this interaction.
- 2) Oral iron products are also associated with decreased tetracycline absorption.
- 3) Oral sodium bicarbonate, kaolin, pectin, or bismuth subsalicylate may impair tetracycline absorption when given together orally.
- 4) Bacteriostatic drugs, like the tetracyclines, may interfere with bactericidal activity of the penicillins, cephalosporins, and aminoglycosides.
- 5) Tetracyclines may depress plasma prothrombin activity and patients on anticoagulant (e.g., warfarin) therapy may need dosage adjustment.
- 6) Tetracyclines have been reported to increase the nephrotoxic effects of methoxyflurane.
- 7) GI side effects may be increased if tetracyclines are administered concurrently with theophylline products.

Pregnancy and Lactation:

- 1) Because tetracyclines can retard fetal skeletal development and discolor deciduous teeth, they should only be used in the last half of pregnancy when the benefits outweigh the fetal risks.
- 2) In a separate system evaluating the safety of drugs in canine and feline pregnancy, this drug has been shown to cause congenital malformations or embryotoxicity.

Side Effect(s) / Adverse Reaction(s):

- 1) Oxytetracycline and tetracycline given to young animals can cause discoloration of bones and teeth to a yellow, brown, or gray color. High dosages or chronic administration may delay bone growth and healing.
- 2) Tetracycline in high levels can exert an antianabolic effect, which can cause an increase in BUN and/or hepatotoxicity, particularly in patients with preexisting renal dysfunction. As renal function deteriorates secondary to drug accumulation, this effect may be exacerbated.
- 3) In ruminants, high oral doses can cause ruminal microflora depression and rumino reticular stasis.
- 4) In small animals, tetracycline can cause nausea, vomiting, anorexia and diarrhea. Cats do not tolerate oral tetracycline or oxytetracycline very well, and may present with symptoms of colic, fever, hair loss and depression. There are reports that long-term tetracycline use may cause urolith formation in dogs.
- 5) Horses who are stressed by surgery, anesthesia, trauma, etc., may break with severe diarrheas after receiving tetracyclines, especially with oral administration.
- 6) Tetracycline therapy (especially long-term) may result in overgrowth (superinfections) of non-susceptible bacteria or fungi.
- 7) Tetracyclines have also been associated with photosensitivity reactions and, rarely, hepatotoxicity or blood dyscrasias.

Environmental Property: Data not available.**Symptoms and Treatment for Overdosage, and Antidote(s):**

Tetracyclines are generally well tolerated after acute overdoses. Oral overdoses would most likely be associated with GI disturbances (vomiting, anorexia, and/or diarrhea). Should the patient develop severe emesis or diarrhea, fluids and electrolytes should be monitored and replaced if necessary. Chronic overdoses may lead to drug accumulation and nephrotoxicity.

Shelf-Life: 2 years from the date of manufacture.**Storage Condition(s):**

Store at temperature below 30°C.

Product Description(s) & Packing(s):

Yellow color powder and without other foreign matter.
Aluminium pouch of 1kg. Paper Bag of 20Kg.

For food producing animals product**Withdrawal Periods**

Swine, chickens and turkeys: 7 days before slaughtering. Cattle and calves: 5 days before slaughtering.

Lambs: 4 days before slaughtering.

Do not administer to lactating dairy cattle.

Maximum Residual Limit (MRL)

All food producing species:

600 µg/kg - kidney

300 µg/kg - liver

100 µg/kg - muscle

200 µg/kg - eggs

100 µg/kg - milk

Disposal:

Dispose of any unused product or containers in accordance with guidance of the local waste regulation authority.

**Made by YSP**

Manufacturer:

Y.S.P INDUSTRIES VIETNAM CO., LTD

Road No.6, Nhon Trach 3 Industrial zone, Nhon Trach,
Dong Nai province, Vietnam Tel: +8461 3569 993

Product Registration Holder :

Y.S.P. INDUSTRIES (M) SDN. BHD.(192593 U)

Lot 3, 5 & 7, Jalan P/7, Section 13,

Kawasan Perindustrian Bandar Baru Bangi,

43000 Kajang, Selangor Darul Ehsan Malaysia.

Product Info: 1 800 88 3679

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