# OXYTET powder 600mg/g

OXP6
draft - 18 Jan 2021

**Ingredient:**
Each g contains:
Oxytetracycline (as Oxytetracycline hydrochloride) ….....……..... 600mg

**Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics):**
**Pharmacodynamics:**
Oxytetracyline 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. Tetracyclines cross the placenta, enter fetal circulation and are distributed into milk. 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):**
By immersion: For skeletal tissues marking of finfish fry and fingerlings.
By feed medication:
Salmonids:For control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *Aeromonas liquefaciens*, and pseudomonas disease.
Catfish: For control of bacterial hemorrhagic septicemia caused by *Aeromonas liquefaciens*, and pseudomonas disease.
Lobster: To control gaffkemia (red tail disease) caused by *Aerococcus viridans.*
Turtles and tortoises: To control ulcerative stomatitis caused by *Vibrio*

**Dosage:**
Immersion(Finfish fry and fingerlings):
Dissolve 0.3~1.1g into every liter of water as buffer solution, immerse the animal for 2~6 hours.
Feed medication:
Salmonids and catfish: Mix 9.3~13.8g into every 100kg of fish, continuous for 10 days
Lobster: Mix 3.7g into every kg of feed, continuous for 5 days.
Turtles and tortoises: Give 0.02g per kg body weight orally, once daily for 7 days.

**Mode of administration:**
1) Orally via medicated feed.
2) Buffered solution for immersion.

**Contraindications:**
1) Contraindicated in patients hypersensitive to it or other tetracycline.
2) 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.

**Precaution(s) / Warning(s):**
1) Do not use oxytetracycline in salmonids when water temperature is below 9°C.
2) Do not use oxytetracycline in catfish when water temperature is below 16.7°C.
3) For use in dry animal feed only. Not for use in liquid feed suplement.

**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

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(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 adminstered 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.
2) High dosages or chronic administration may delay bone growth and healing.
3) 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.
4) In ruminants, high oral doses can cause ruminal microflora depression and ruminoreticular stasis.
5) In small animals, tetracycline can cause nausea, vomiting, anorexia and diarrhea.
6) Cats do not tolerate oral tetracycline or oxytetracycline very well, and may present with symptoms of colic, fever, hair loss and depression.
7) Long-term tetracycline use may cause urolith formation in dogs.
8) Horses who are stressed by surgery, anesthesia, trauma, etc., may break with severe diarrheas after receiving tetracyclines, especially with oral administration.
9) Tetracycline therapy (especially long-term) may result in overgrowth (superinfections) of non-susceptible bacteria or fungi.
10) Tetracyclines have also been associated with photosensitivity reactions and, rarely, hepatotoxicity or blood dyscrasias.

**Environment property:**
The environment characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

**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.

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**Shelf-Life:**
3 years.

**Product Description and Packing(s):**
Yellow color powder, and without other foreign matter.
Aluminum Pouch of 100g, 1Kg, Plastic (HDPE) Drum of 5Kg.

**For food producing animals product:**
**Withdrawal Periods**
Salmonids and catfish: 21 days before harvesting.
Lobster: 30 days before harvesting.

**Maximum Residual Limit (MRL):**
Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, finfish and lobster. Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follow:
2 ppm in muscle
6 ppm in liver
12 ppm in fat and kidney
0.3ppm in milk

To be used by or on the order of a licensed veterinarian.
**Storage:** Store at temperature below 30ºC.
**Disposal**:
Dispose of any unused product or containers in accordance with guidance of the local waste regulation authority.
Keep medicine out of reach of children / Jauhkan daripada kanak-kanak.

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