

Trevidox Capsules



Composition:

Each Capsule Trevidox contains: Doxycycline Hyclate equivalent to Doxycycline 50 - 75 - 100 - 150 mg.

Pharmacological Classification:

Antibiotics - Tetracycline.

Intended Use (Common Use of the Drug):

Doxycycline is used to treat bacterial infections for some negative and positive bacteria.

Mechanism of Action:

Doxycycline inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit. Doxycycline has bacteriostatic activity against a broad range of Gram-positive and Gram-negative bacteria.

Pharmacokinetics:

Doxycycline is readily absorbed and are bound to plasma proteins in varying degrees. Doxycycline concentrated by the liver in the bile and excreted in the urine and feces at high concentrations in a biologically active form. Doxycycline is virtually completely absorbed after oral administration. Excretion of doxycycline by the kidney is about 40%/72 hours in individuals with normal function (creatinine clearance about 75 mL/min). This percentage excretion may fall as low as 1-5%/72 hours in individuals with severe renal insufficiency (creatinine clearance below 10 mL/min). Studies have shown no significant difference in serum half-life of doxycycline (range 18-22 hours) in individuals with normal and severely impaired renal function. Hemodialysis does not alter serum half-life.

Indications:

- Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.
- Trevidox is used to treat many different types of infections including:
 - chest, lung or nasal infections e.g., bronchitis, pneumonia, sinusitis.
 - urinary tract infections (the passage through which urine passes) e.g., cystitis, urethritis.
 - eye infections.
 - sexually transmitted diseases e.g., gonorrhoea, syphilis, chlamydia.
 - fevers associated with louse or tick bites.
 - malaria, when chloroquine is not effective.
- Trevidox is also used to prevent certain infections developing; these are scrub typhus (a disease carried by small insects), Rocky Mountain spotted fever, travellers' diarrhoea, malaria, cholera and leptospirosis (a bacterial infection from contaminated water).

Contraindications:

This drug Contraindicated if you are hypersensitive to the active substance or any of the excipients.

Side effects:

- Like all medicines, this one can cause side effects, although not everyone experiences them.
- Gastrointestinal disorders: Anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, and inflammatory lesions (with monilial overgrowth) in the anogenital region.
- Skin disorders: Maculopapular and erythematous rashes, Stevens-Johnson syndrome, toxic epidermal necrolysis, and erythema multiforme have been reported. Exfoliative dermatitis has been reported but is uncommon, photosensitivity.
- Renal Toxicity: Rise in BUN.
- Hypersensitivity Reactions: Urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, serum sickness, pericarditis, and exacerbation

of systemic lupus erythematosus.

- Blood disorders: Hemolytic anemia, thrombocytopenia, neutropenia, and eosinophilia.
- Other: Intracranial hypertension (IH, pseudotumor cerebri) has been associated with the use of tetracyclines.
- Inform your doctor or pharmacist if you experience any side effects not listed in this leaflet.

Warnings & Precautions:

- The use of drugs of the tetracycline class, including doxycycline, during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of the drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported.
- Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Trevidox, and may range in severity from mild diarrhea to fatal colitis.
- All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in the fibula growth rate has been observed in premature given oral tetracycline in doses of 25 mg/kg every six hours; this reaction was shown to be reversible when the drug was discontinued.
- Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development).
- Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients apt to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs, and treatment should be discontinued at the first evidence of skin erythema.
- All patients taking doxycycline should be advised:
 - to avoid excessive sunlight or artificial ultraviolet light while receiving doxycycline and to discontinue therapy if phototoxicity (e.g., skin eruptions, etc.) occurs. Sunscreen or sunblock should be considered.
 - to drink fluids liberally along with doxycycline to reduce the risk of esophageal irritation and ulceration.
 - hat the use of doxycycline might increase the incidence of vaginal candidiasis.

Drug and Food Interactions:

- Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.
 - Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.
 - Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracyclines in conjunction with penicillin.
 - The absorption of tetracyclines is affected by taking antacids containing aluminum, calcium, or magnesium, or preparations containing iron (as an unabsorbable complex is formed).
 - The absorption of tetracyclines is decreased when given concomitantly with milk and dairy products containing calcium.
 - Barbiturates, carbamazepine, and phenytoin decrease the half-life of doxycycline.
 - Concurrent use of tetracycline may render oral contraceptives less effective.
- Pregnancy & Lactation & Fertility:**
- Pregnancy:** Pregnancy category D, there are no adequate and well-controlled studies on the use of doxycycline in pregnancy woman.
- Lactation:** Doxycycline is excreted in human milk, but the extent of doxycycline absorption by the infant is unknown. Short-term use of

doxycycline by a nursing woman is not contraindicated; however, the effects of prolonged exposure to doxycycline in human milk are unknown. Because of the potential for adverse reactions in nursing infants due to doxycycline, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Fertility: Effect on male fertility has not been studied.

Effects on ability to drive and use machines:

Doxycycline is not known to affect your ability to drive or operate machinery.

Doses and method of use:

- Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.

Adults: The usual dose of oral doxycycline is 200 mg on the first day of treatment (administered 100 mg every 12 hours or 50 mg every 6 hours) followed by a maintenance dose of 100 mg/day. The maintenance dose may be administered as a single dose or as 50 mg every 12 hours. In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg every 12 hours is recommended.

Pediatric Patients: For all pediatric patients weighing less than 45 kg with severe or life-threatening infections (eg, anthrax, Rocky Mountain spotted fever), the recommended dose is 2.2 mg/kg body weight given every 12 hours. Children weighing 45 kg or more should receive the adult dose.

Uncomplicated Gonococcal infections in adults (except anorectal infections in men): 100 mg, by mouth, twice a day for 7 days.

Acute epididymo-orchitis caused by N. gonorrhoeae: 100 mg, by mouth, twice a day for at least 10 days.

Primary and secondary syphilis: 300 mg a day in divided doses for at least 10 days.

Uncomplicated urethral, endocervical, or rectal infection in adults caused by Chlamydia trachomatis: 100 mg, by mouth, twice a day for at least 7 days.

Nongonococcal urethritis caused by C. trachomatis and U. urealyticum: 100 mg, by mouth, twice a day for at least 7 days.

Acute epididymo-orchitis caused by C. trachomatis: 100 mg, by mouth, twice a day for at least 10 days.

Inhalational anthrax (post-exposure): Adults: 100 mg of doxycycline, by mouth, twice a day for 60 days. Children weighing less than 45 kg 2.2 mg/kg of body weight, by mouth, twice a day for 60 days.

Children weighing 45 kg or more should receive the adult dose.

Usage in renal impairment: The half-life of doxycycline is not significantly altered in patients with severely impaired renal function.

- Inform your doctor or pharmacist if you forget take medicine and before stopping its use.

Overdoses and toxicity and treatment:

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Dialysis does not alter serum half-life, and it would not be of benefit in treating cases of overdosage.

Physical Properties:

Hard gelatin capsules, yellow/gray, size 2.

Storage Conditions:

Store at a temperature below 25° C.

Keep out of reach of children.

Packaging:

Each Trevidox 50 - 75 - 100 -150 mg carton box contains 20 Capsule in two blister strips.

