

Doxycycline Hyclate

VITER04-0

Teradox 100 mg Capsule Antibacterial

DESCRIPTION

Light green and pink capsule with "DXY 100" printed on one end and "HD" printed on the other, with yellow filled material.

FORMULATION

Doxycycline hyclate equivalent to Doxycycline 100 mg / capsule.

ACTIONS AND PHARMACOLOGY

Doxycycline is a bacteriostatic agent, with a wide range of anti-microbial activity. It interferes with bacterial protein synthesis by reversibly binding to bacterial 30S ribosomal subunit, thus preventing the binding of aminoacyl transfer-RNA to the messenger-RNA ribosome complex. Doxycycline is readily absorbed from the gastro-intestinal tract and is excreted mainly in urine.

PHARMACOKINETICS

Doxycycline is readily and almost completely absorbed from the gastrointestinal tract and absorption is not significantly affected by the presence of milk or food in the stomach or duodenum. Mean plasma concentrations of 2.6 mcg/mL have been reported 2 hours after a 200 mg oral dose, falling to 1.45 mcg/mL at 24 hours. About 80-95 % of doxycycline in the circulation is reported to be bound to plasma proteins. Its biological half-life varies from about 12 to 24 hours. Its widely distributed in body tissues and fluids. The majority of a dose of doxycycline is excreted in the faeces after chelation in the intestines. Doxycycline is stated not to accumulate significantly in patients with renal impairment, although excretion in the urine is reduced; increased amounts of doxycycline are excreted in the faeces in these patients.

INDICATIONS

Doxycycline Capsules are indicated for the treatment of the following infections:

- Rickettsial infections, including typhus, Rocky Mountain spotted fever and Q fever.
- Chlamydial infections, including psittacosis, lymphogranuloma venereum, trachoma and inclusion conjunctivitis.
- Mycoplasma infections, especially those caused by *Mycoplasma pneumoniae*.
- Brucellosis and plague (use in association with streptomycin).
- Tularaemia, chancroid, granuloma inguinale, urinary tract infections, acne.
- Cholera, relapsing fever, leptospirosis and early stage of Lyme disease.
- Balantidiasis, amoebic dysentery (use in association with an amoebicide).
- Syphilis, yaws, gonorrhoea, actinomycosis, anthrax, rat-bite fever and acute necrotising ulcerative gingivitis.
- Chloroquine resistant falciparum malaria.

DOSAGE AND ADMINISTRATION

- **For susceptible infections:**
Adults: Oral, 200 mg on the first day, then 100 mg once a day.
- **In severe infections:**
Adults: Oral, 200 mg on the first day and maintained throughout the course of treatment.
- **Uncomplicated gonococcal infections:**
Adults: Oral, 100 mg twice daily for 7 days.
- **Syphilis in penicillin-allergic patients:**
Adults: Oral, 100 to 200 mg twice daily for at least 14 days.
- **Relapsing fever and louse-borne typhus:**
Adults: Oral, 100 to 200 mg may be given as a single dose.
- **Prophylaxis of scrub typhus:**
Adults: Oral, 200 mg may be given as a single dose.
- **Prophylaxis of leptospirosis:**
Adults: Oral, 200 mg may be given orally once a week throughout exposure for up to 21 days and 200 mg is also given when leaving the area of infection risk.
- **Chloroquine-resistant falciparum malaria:**
Adults: Oral, 200 mg daily for at least 7 days after treatment with quinine.
- **For treatment and post-exposure prophylaxis of inhalation anthrax:**
Adults: Oral, 100 mg twice daily for a 60-day course treatment may be used.
- **Acne vulgaris:**
Adults: Oral, 50 mg daily for 6 to 12 weeks.

Note:

Effect of doxycycline on teeth should be considered. Therapy should be continued for at least 10 days in group A beta-haemolytic streptococcal infections.

CONTRAINDICATIONS

- Avoid in patients who have shown hypersensitivity to tetracyclines.
- Use is not recommended during the last half of pregnancy, nursing mothers and children under the age of 8 years as tetracyclines may cause permanent discolouration of the teeth, enamel hypoplasia and inhibition of linear skeletal growth.

PRECAUTIONS

- Care must be taken when liver function is impaired.
- May interfere with some diagnostic tests including determination of urine catecholamines or glucose.
- Unsafe in patients with porphyria.
- Oesophageal ulceration may be a particular problem if capsules are taken with insufficient fluid or in a recumbent posture.

USE IN PREGNANCY AND LACTATION

Use is not recommended during the last half of pregnancy and nursing mothers.

ADVERSE EFFECTS

- Nausea, vomiting and diarrhoea.
- Discoloration of infant's or children's teeth.
- Cramps or burning sensation of the stomach.
- Sore mouth or tongue (fungal overgrowth, hypertrophy of the papilla).
- Increased sensitivity to sunlight.
- Itching of the rectal or genital areas.
- Hepatotoxicity.
- Leukocytosis, neutropenia, leukopenia, atypical lymphocytes, toxic granulation of granulocytes, haemolytic anaemia, thrombocytopenia and thrombocytopenic purpura has occurred.

DRUG INTERACTIONS

- Alkalis, aluminium hydroxide, bismuth, calcium, zinc, iron and magnesium diminish the absorption of doxycycline.
- Concurrent use with penicillin, barbiturates, carbamazepine, phenytoin and sodium bicarbonate is not recommended.
- Hepatotoxic and nephrotoxic drugs should not be given with doxycycline.

OVERDOSAGE

Clinical features

Nausea, anorexia, diarrhoea, perianal itching, skin eruption, fever, anaphylaxis and liver damage.

Treatment

Emesis or gastric lavage, if appropriate; with the necessary emergency measures, if required.

Caution

Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction report to the fda: www.fda.gov/ph

Storage

Store at temperatures not exceeding 25°C. Protect from light and moisture.

Availability

Alu / Clear PVC blister pack x 10's (Box of 100's)

Reg. No.: DR-X42665

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Manufactured by:

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121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
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Imported & Distributed by:

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