CTD MODULE 1 ADMINISTRATIVE INFORMATION AND PRODUCT INFORMATION	
Product Name :	**TETRAREN CAPSULES** **(Tetracycline Hydrochloride 250mg)**

Pack Insert:

TETRAREN CAPSULES 250 MG

COMPOSITION

Tetracycline Hydrochloride BP 250 mg

PHARMACEUTICAL FORM

Capsule

CLINICAL PARTICULARS

Therapeutic indications

For the treatment of infections due to sensitive organisms and particularly those affecting the respiratory tract, gastro-intestinal tract and genito-urinary tract, and infections of the skin and soft tissues.

Prophylactically before or after dental and/or surgical procedures.

Posology and method of administration

Capsules should be swallowed whole with a glass of water one hour before or two hours after a meal. Adults: 1 g per day in four divided doses of 250 mg or two divided doses of 500 mg each. Higher doses may be required to control acute episodes. Acute gonococcal urethritis 500 mg three times daily for one or two days. Female patients require more prolonged therapy. Acne: 500mg twice daily. If no improvement is seen after the first three months another oral antibiotic should be used. Children: Not recommended for children under 12 years of age. Usual dose for children of 12 years and above: 25 mg/kg/day in 4 divided doses. Children weighing more than 40 kgs should be given the recommended adult dose.

Contraindications

Known hypersensitivity to tetracyclines. Renal impairment. Children under 12 years of age. Use during pregnancy or lactation.

Special warnings and precautions for use

In renal impairment small doses of the drug may lead to systemic accumulation with possible hepatic toxicity. Under these circumstances lower doses are indicated and tetracycline serum level determinations are advisable. Likewise in patients with hepatic dysfunction or when they are taking other potentially hepatotoxic drugs. Tetracycline should not be administered to children because a yellow-brown discolouration of the teeth may occur. Enamel hypoplasia has been reported. Photosensitivity reactions can sometimes occur. Susceptible patients should avoid direct exposure to natural or artificial sunlight and discontinue therapy at the first sign of skin discomfort. Weak neuromuscular blockade may occur in patients suffering from Myasthenia Gravis. Exacerbation of SLE (systemic lupus erythematosus) may occur. In common with all antibiotics overgrowth of non-susceptible or resistant organisms may occur. Both cross-sensitisation in patients and cross-resistance between tetracyclines may develop.Increased intra-cranial pressure, with bulging of the fontanelles has occasionally occurred in infants. This condition rapidly disappears when the drug is withdrawn.

Interaction with other medicinal products and other forms of interaction

Patients receiving concurrent anti-coagulant therapy should have the doses of those drugs reduced because tetracycline depresses plasma prothrombin activity. The anaesthetic methoxyflurane increases the risk of kidney failure.Atovaquone plasma concentration is reduced by tetracycline. Tetracyclines bind to di-/tri-valent cations. Absorption from the gastrointestinal tract is impaired by the concomitant administration of iron, calcium, aluminium, magnesium, bismuth and zinc salts