

PACKAGE LEAFLET

DOXYCYCLIN

capsules

Doxycycline

COMPOSITION

Capsules containing Doxycycline hydrochloride equivalent to 100 mg Doxycycline.

PROPERTIES AND ANTIMICROBIAL SPECTRUM

Doxycycline is an oral wide-spectrum semisynthetic antibiotic, belonging to the group of tetracyclines with pronounced bacteriostatic activity. The antibiotic suppresses the protein synthesis in the microbial cell by tRNA and mRNA binding in the ribosomal complex. Doxycycline possesses broad antimicrobial spectrum, similar to tetracyclin. The antibiotic displays high activity against *Brucella*, *Pasteurella*, *Chlamydia*, *Mycoplasma pneumoniae*, *Rickettsia*, *Neisseria gonorrhoeae*, *Treponema*, *Spirocheta*, *Vibrio cholerae*, *Corynebacterium acnae*. Doxycycline is used for the treatment of infections caused by *Staphylococcus*, *Streptococcus*, *Pneumococcus*, *Salmonella typhi*, *Shigella*, *Klebsiella*, *Morganella morgani*, *Escherichia coli*, *Haemophilus influenzae*, *Clostridium*, *Bacteroides*, *Fusobacterium*, *Legionella pneumophila*. Laboratory sensitivity to Doxycycline should be determined on isolation of the causative microorganism due to the increased resistance to many strains of the aforementioned microorganisms.

PHARMACOKINETICS

Doxycycline is rapidly absorbed and almost entirely (up to 90-100%) from the gastrointestinal tract. Food does not interfere considerably with its absorption. Though, the absorption is reduced significantly by dairy products due to the calcium content, which takes part in the formation of chelate compounds. Peak plasma concentrations of 2-4 µg/ml are attained within 2-4 hours after oral administration of 200 mg Doxycycline, and 24 hours after the intake the plasma concentrations are approx. 1 µg/ml. The drug's plasma half-life varies from 15 to 22 hours and is not altered in case of renal impairment. The antibiotic becomes bound to the plasma proteins to the extent of between 85 and 96%. Doxycycline well penetrates in the body tissues and fluids and attains high concentrations in the bile, sputum, pleural, ascite and synovial fluid. Therapeutic concentrations of the drug are maintained in the lungs, adnexa, prostate, testes and liver. The antibiotic accumulates in the bones and teeth. It crosses the placental barrier and is excreted in the breast-milk. Doxycycline penetrates in the cerebrospinal fluid in very low concentrations unless the meninges are not inflamed. The drug becomes metabolized in the liver. Part of the antibiotic is reabsorbed from the intestines and further included in the enterohepatal circulation. In contrast to the other tetracyclines, Doxycycline is excreted predominantly in the gastrointestinal tract (up to 70%). This antibiotic is a drug of choice in cases of extrarenal infections in presence of renal insufficiency.

INDICATIONS

Doxycycline is suitable for the treatment of infections, caused by Doxycycline - susceptible microorganisms:

- **respiratory tract infections** - tonsillitis, pharyngitis, otitis, sinusitis, bronchitis, pneumonia, bronchopneumonia;

- biliary tract infection;
- **urogenital infections** - urethritis, cystitis, pyelonephritis, prostatitis;
- infections of the pelvis ;
- **intestinal infections** - intestinal amebiasis and etc.;
- infections of the skin and soft tissues - impetigo, cellulitis, furunculosis, acne, infected traumatic and post-operative wounds;
- **other infections** - osteomyelitis, thrombophlebitis, ophthalmia.

CONTRAINDICATIONS

Hypersensitivity to tetracyclines. Severe liver impairment. Children under 8 years of age. Pregnancy and breast-feeding.

ADVERSE EFFECTS

Doxycycline may cause nausea, vomiting, diarrhoea. Long-term high-dose administration of the antibiotic may cause ulcers on the esophageal mucosa, glossitis, oral candidiasis. Rarely, liver lesions and transitory changes in the hematological indices may be encountered. Doxycycline may cause photosensibilisation. Skin allergic reactions and in rare cases other severe allergic reactions (anaphylaxis, Quincke's edema) have been observed during Doxycycline treatment.

PRECAUTIONS

Doxycycline should cautiously be employed in presence of damaged liver function (due to risk of accumulation), in patients with impaired esophageal mucosa, ulcer of the stomach and duodenum, intensive sun irradiation.

DRUG INTERACTIONS

Antiacid preparations containing calcium, magnesium or aluminium or iron containing preparations may reduce considerably Doxycycline absorption.

Doxycycline enhances the hepatotoxic and nephrotoxic effects of lithium salts, general anaesthetics and other preparations possessing similar effect.

Doxycycline may potentiate the anticoagulant activity of indirect anticoagulant.

Concomitant administration of enzyme inducers may decrease the chemotherapeutic effect of Doxycycline.

DOSAGE AND MODE OF ADMINISTRATION

Doxycycline should not be taken immediately before bed-time and should be swallowed with sufficient amount of liquid in order to avoid its ulcerous effect on esophagus.

The usual dosage for adults is 100 mg every 12 hours for the first day and 100 mg every 24 hours for the next days. On physician's prescription could be taken 100 mg every 12 hours during the whole therapy regimen. In gonococcal urethritis in man the treatment is carried out with an initial dose of 300 mg for the first day and further maintenance dose of 200 mg in 2 intakes for 2-4 more days.

In primary and secondary syphilis the treatment is carried out with a dose of 300 mg daily in 3 intakes in the course of 10 days.

Children over 8 years should be given daily dosage of 4 mg/kg body weight.

In patients with renal insufficiency the excretion of the preparation in the urine is reduced on account of the increased excretion with the feces. Therefore, the antibiotic can be used in patients with renal insufficiency.

PACKAGE

Capsules of 100 mg; blisters of 6 capsules in boxes.

STORAGE

In dry places, protected from direct sunlight, at temperature not exceeding 30°C.

SHELF LIFE

Four years.

MANUFACTURED BY:

Balkanpharma - Razgrad, Bulgaria.