COMPOSITION

One capsule of 75 mg contains 75 mg Clindamycin (as hydrochloride).

One capsule of 150 mg contains 150 mg Clindamycin (as hydrochloride).

PROPERTIES AND ANTIMICROBIAL SPECTRUM

Clindamycin is a bacteriostatic antibiotic, belonging to the group of lincosamides. It inhibits the protein synthesis of bacteria at the level of 50S - ribosomal subunit.

The antibacterial spectrum of Clindamycin includes:

- **aerobic gram-positive cocci** - Staphylococcus sp.(penicillinase and non-producing strains), Streptococcus sp. (except for Streptococcus faecalis), Pneumococcus;

- **anaerobic gram-negative bacilli** - Bacteroides sp., (including Bacteroides fragilis group and Bacteroides melaninogenicus group), Fusobacterium sp.

- **anaerobic gram positive nonsporeforming bacilli** - Propionibacterium, Eubacterium Actinomyces sp.

- **anaerobic and microaerophilic gram-positive cocci** - Peptococcus sp. Peptostreptococcus sp., Microaerophilic streptococci, Clostridium perfringens.
Clindamycin possesses antiprotozoic activity in pneumonia, caused by Pneumocystis carinii.

**PHARMACOKINETICS**

The antibiotic is rapidly and almost entirely absorbed (up to 90% of the dose applied) from the gastrointestinal tract. Food does not interfere considerably with its absorption. Maximum plasma concentrations of the drug are attained within 1 - 3 h after oral administration. The plasma half-life of Clindamycin is approximately 2.5 - 3 h. The drug binds to the plasma proteins to a great extent (up to 90%). Clindamycin well penetrates in the body tissues and fluids, attaining high concentrations in the bones, prostate, bile, urine, sputum and pleural fluid. The antibiotic hardly penetrates the blood-brain barrier. It crosses the placenta and passes into the breast-milk. Clindamycin is metabolized in the liver. Part of its metabolites possesses antibacterial activity. Approximately 10% of the dose employed are eliminated with the urine and up to 4% - with the bile as an active drug, the remaining amount of the antibiotic - as inactive metabolites.

**INDICATIONS**

Clindamycin is indicated for the treatment of severe infections, caused by Clindamycin - susceptible microorganisms:

- **lower respiratory tract infections** - pneumonia, empyema, pulmonary abscesses;

- otorhinolaryngological infections;

- **intraabdominal infections** - peritonitis, intraabdominal abscesses;
- gynecological infections - endometritis, non-gonococcal tuboovarial abscesses, pelvic cellulitis; post-operative vaginal infections, caused by anaerobes;

- infections of the bones and joints; and as a part of surgical combined therapy in chronic infections of the bones and joints;

- sepsis - caused by Staphylococcus aureus, Streptococcus (except for Streptococcus faecalis) and Clindamycin-susceptible anaerobes.

**CONTRAINDICATIONS**

Clindamycin is contraindicated for patients with known hypersensitivity to lincozamides; patients with colitis and diarrhoea; severe impairment of the renal and liver functions; newborns and prematurely born infants.

**ADVERSE EFFECTS**

Gastrointestinal disorders, e.g. nausea, vomiting, diarrhoea, pseudomembranous colitis may occur with Clindamycin treatment.

In rare cases may be encountered impairment in the liver functions, ulcers on the esophageal mucosa, transitory changes in the hematological indices, suppressive effect on the neuro-muscular transmission. Skin eruptions and erythema are also possible to appear. Clindamycin capsules should be swallowed with a glass of water in order to avoid the irritation of esophagus.

**PRECAUTIONS**

Clindamycin use during pregnancy and breast-feeding is contraindicated.

Great care should be taken with patients prone to diarrhoea, patients with myasthenia, bronchial asthma or other allergies, in case of pre-existing liver and renal impairment.
If symptoms of diarrhoea or colitis emerge, Clindamycin use should be withdrawn at once and infusion of liquids, electrolytes and proteins should be instituted instead. Due to its poor penetration in the liquor, Clindamycin should not be used in the treatment of meningitis, even in case of proven laboratory sensitivity to the isolated causative microorganism.

**DRUG INTERACTIONS**

Due to the antagonism between Clindamycin and erythromycin, simultaneous use of the two drugs is contraindicated.

The therapeutic efficacy of Clindamycin may be reduced considerably by absorbents or cholestiramine.

Clindamycin may intensify the suppressive effect of myorelaxants, general anaesthetics, polymixins and aminoglycosides on the neuro-muscular transmission.

The antibiotic may enhance the suppressive effect of narcotic analgesics on the respiratory center.

Co-administration of spasmylytics may result in toxic megacolon.

Clindamycin may reduce the therapeutic efficacy of anticholinesterase agents, administered to patients with muscular weakness.

**DOSAGE AND MODE OF ADMINISTRATION**

Clindamycin is administered orally in the following doses:

**For adults:** 150 mg or 300 mg every 6 hours. In severe cases - 300-450 mg every 6 hours;
For children over 1 month of age: 8-16 mg/kg/ for 24 h, divided in 3-4 intakes. In severe cases - 16-20 mg/kg for 24 h, divided in 3-4 intakes.

The capsules should be swallowed with sufficient quantity of liquid.

The treatment duration varies broadly, depending on the nature of the underlying process, for example the prophylaxis of rheumatic recurrence lasts for at least 10 days.

PACKAGE

Capsules of 75 mg and 150 mg; blister strips of 8 capsules; boxes of 2 blister strips.

Capsules of 75 mg and 150 mg; boxes of 1000.

STORAGE

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

SHELF LIFE

Three years.

MANUFACTURED BY:

Balkanpharma - Razgrad, Bulgaria.