To reduce the development of drug-resistant bacteria and maintain the effectiveness of clindamycin hydrochloride capsules, USP and other antibacterial drugs, clindamycin hydrochloride capsules, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.  

**CLINDAMYCIN HYDROCHLORIDE**

Clindamycin hydrochloride has been associated with severe colitis which may lead to fatal outcome, especially in older patients. Treatment with antibacterial agents alters the normal flora of the colon and decreases competitive inhibition of the overgrowth of clostridia. Clindamycin should be used with great caution in the following conditions and only by physicians experienced in the treatment of pseudomembranous colitis: bowel condition where the normal host defenses are impaired, such as acquired immune deficiency syndrome (AIDS), extensive, prolonged gastrointestinal surgery, radiation enteritis, regional enteritis, or ulcerative colitis. Treatment should be given only by physicians experienced in the treatment of pseudomembranous colitis. The diagnosis of pseudomembranous colitis should be confirmed by a fecal specimen before initiating therapy.

**CONTRAINDICATIONS**

Clindamycin hydrochloride is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.

**PRECAUTIONS**

**A.** Not for use in patients who are sensitive to the antibiotics that are C. difficile toxin A or toxin B precursors. Clindamycin hydrochloride is not effective in removing clindamycin from the serum.

**B.** Xerostomia.

**C.** The chemical name for clindamycin hydrochloride is methyl 7-chloro-1-thio-L-threo-3,4-dihydroxy-4-methyl-2-pyrrolidinonecarboxylic acid hydrochloride.

**DESCRIPTION**

Clindamycin hydrochloride is the hydrated hydrochloride salt of clindamycin. Clindamycin is a semisynthetic antibiotic produced by a (7S)-chloro-substitution of the (7R)-hydroxyl group of the parent compound lincomycin.

**CLINICAL PHARMACOLOGY**

**Absorption**

Serum level studies with a 150 mg oral dose of clindamycin hydrochloride in 24 normal adult volunteers showed that clindamycin was rapidly absorbed after oral administration. An average peak serum level of 1.5 mcg/mL (range 0.9 to 2.3 mcg/mL) was reached in 45 minutes; serum levels averaged 1.5 mcg/mL at 3 hours and 0.7 mcg/mL at 6 hours. Absorption of an oral dose is virtually complete (98%) and the concomitant administration of food does not appreciably modify the serum concentrations; serum levels have been uniform and predictable from person to person and dose to dose. Serum level studies following multiple doses of clindamycin hydrochloride for up to 14 days show no evidence of accumulation or altered metabolism of drug. Doses of up to 2 grams of clindamycin per day for 14 days have been well tolerated by healthy volunteers, except that the incidence of gastrointestinal side effects is greater with the higher doses.

**Distribution**

Concentrations of clindamycin in the serum increased linearly with increased dose. Serum levels exceed the MIC (minimum inhibitory concentration) for most indicated organisms, both in vitro and in clinical infections, as described in the INDICATIONS AND USAGE section.

**Metabolism**

Approximately 10% of the administered dose of clindamycin is excreted in the urine as unchanged drug. The remainder is excreted as metabolites. The metabolites of clindamycin are not antibacterially active.

**Elimination**

Approximately 10% of the administered dose of clindamycin is excreted in the urine as unchanged drug. The remainder is excreted as metabolites. The metabolites of clindamycin are not antibacterially active.

**KINETICS**

The average biological half-life is 2.4 hours. Approximately 10% of the administered dose of clindamycin is excreted in the urine as unchanged drug. The remainder is excreted as metabolites. The metabolites of clindamycin are not antibacterially active.

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WARNINGS

See BOXED WARNING.

Clindamycin associated diarrhea

Clindamycin associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of Clostridium difficile, which carries a potential risk of developing Clostridium difficile colitis. Anti-diarrheal agents may delay CDAD but may also mask its symptoms.

If symptoms of pseudomembranous colitis occur, oral and intravenous broad-spectrum antibiotics should be used with caution. Use of C. difficile toxins A and B, which contribute to the development of CDAD, may be present in the stool of infected patients, even in the absence of diarrhea.

Precautions

General

Review of experience to date suggests that a subgroup of older patients with associated severe illness may tolerate diarrhea less well. When clindamycin is indicated in these patients, they should be carefully monitored for signs of colitis. Clindamycin hydrochloride should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. Clindamycin hydrochloride should be prescribed with caution in atopic individuals.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy. The use of clindamycin hydrochloride occasionally results in overgrowth of nonresistant organisms—particularly yeasts. Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Clindamycin dosage modification may not be necessary in patients with renal disease. In patients with moderate to severe liver disease, prolongation of clindamycin half-life has been found. However, it was postulated from studies that when given every eight hours, accumulation should rarely occur. Therefore, dosage modification in patients with liver disease may not be necessary. However, periodic liver enzyme determinations should be made when treating patients with severe liver disease.

Prescribing clindamycin hydrochloride capsules, USP in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Information for Patients

Patients should be counseled that antibacterial drugs, including clindamycin hydrochloride capsules, USP, should only be used to treat bacterial infections. Do not treat viral infections (e.g., common cold). When clindamycin hydrochloride capsules, USP are prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by clindamycin hydrochloride capsules, USP or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after antibiotic treatment diarrhea may occur which usually does not last beyond 2 or 3 days. If the diarrhea persists beyond 2 or 3 days, one should consult his physician.

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