Clindamycin Palmitate Hydrochloride for Oral Solution, USP

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Clindamycin Palmitate Hydrochloride for Oral Solution and other antibacterial drugs, Clindamycin Palmitate Hydrochloride for Oral Solution should be used only to treat or prevent infections that are known or strongly suspected to be caused by bacteria.

**Warning**

Clindamycin and lincomycin are similar in their antibacterial spectra. Microorganisms may develop resistance during treatment with Clindamycin Palmitate Hydrochloride for Oral Solution if used to treat or prevent infections caused by bacteria that are not susceptible to clindamycin. Therefore, Clindamycin Palmitate Hydrochloride for Oral Solution should be used only to treat or prevent infections that are known or strongly suspected to be caused by bacteria. If therapy with Clindamycin Palmitate Hydrochloride for Oral Solution is continued for more than 24 to 48 hours in patients with osteomyelitis, endocarditis, or septicemia, cultures should be obtained to determine susceptibility to antimicrobial therapy and may require colectomy.

**INDICATIONS AND USAGE**

Clindamycin Palmitate Hydrochloride for Oral Solution is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria. Clindamycin Palmitate Hydrochloride for Oral Solution is contraindicated in individuals with a history of anaphylaxis to any clindamycin or lincomycin derivative. Clindamycin has been associated with potentially fatal gastrointestinal toxicity (see WARNINGS). Before selecting clindamycin the physician should consider the nature of the infection and the suitability of less toxic alternatives (e.g., erythromycin). If Clindamycin Palmitate Hydrochloride for Oral Solution is used to treat a presumptively bacterial infection in which anaerobic bacteria may be involved, appropriate culture and therapy should be instituted as clinically indicated.

**DOSAGE AND ADMINISTRATION**

**Adults and Children 12 Years of Age and Older.**

**Dosage:**

Dosage should be determined by the nature of the infection and the susceptibility of the causative organisms. The dosage and frequency of administration of Clindamycin Palmitate Hydrochloride for Oral Solution should be adjusted according to the clinical response of the patient. The dosage of clindamycin that will optimally maintain therapeutic levels in serum is also influenced by the susceptibility of the causative organisms and the nature and severity of the infection. It is important to use the least toxic alternate drug. See table below for dosages and dosing intervals of the various clindamycin dosage forms.

**Recommended Dosage Ranges for Various Anaerobic Infections**

**Serious Anaerobic Infections:**

- **Bone and Joint Infections:**
  - Clindamycin palmitate HCl: 3 mg/kg every 6 hours. The dosage and frequency of administration should be adjusted according to the clinical response of the patient.
  - Clindamycin phosphate: 180 mg every 6 hours. The dosage and frequency of administration should be adjusted according to the clinical response of the patient. Tetracycline: 250 to 500 mg every 6 hours. The dosage and frequency of administration should be adjusted according to the clinical response of the patient.

- **Pelvic Infections:**
  - Clindamycin palmitate HCl: 3 mg/kg every 6 hours. The dosage and frequency of administration should be adjusted according to the clinical response of the patient.
  - Clindamycin phosphate: 300 mg every 6 hours. The dosage and frequency of administration should be adjusted according to the clinical response of the patient.

- **Other Anaerobic Infections:**
  - Clindamycin palmitate HCl: 3 mg/kg every 6 hours. The dosage and frequency of administration should be adjusted according to the clinical response of the patient.
  - Clindamycin phosphate: 150 mg (6 mg/kg) every 6 hours. The dosage and frequency of administration should be adjusted according to the clinical response of the patient.

**Pediatric Patients:**

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other reported clinical experience indicates that antibiotic- treated infections 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 observed, but it was extrapolated from studies that when given every eight hours, accumulation should rarely occur. Therefore, dosage modification in patients with moderate or severe liver disease and a patient’s medication status is needed to determine if lower dosage and/or more frequent administration is required when treating patients with these conditions.

Prescribing Clindamycin Palmitate Hydrochloride for Oral Solution in the absence of a proven or strongly suggested 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 informed that antibiotic drugs including Clindamycin Palmitate Hydrochloride for Oral Solu- tion may cause diarrhea, which sometimes may be severe. The patient should be told that it is common to feel better in the first few days of treatment, but that the diarrhea may recur when the medication is stopped. If this occurs, patients should contact their physician as soon as possible.

Laboratory Tests

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Some patients, however, in clinically appropriate circumstances, the physician may elect to initiate treatment or continue treatment with clindamycin until the infection is controlled. If mild to moderate diarrhea persists past the first 2 days of therapy, it is advisable to discontinue clindamycin.

Clindamycin Palmitate Hydrochloride for Oral Solution is usually well tolerated. No appreciable toxic manifestations were observed after administration of the drug to volunteers at doses of up to 100 times the maximum recommended dose.

Hematological: Agranulocytosis has been associated with the use of clindamycin. When clindamycin is indicated in patients with a history of allergy, the possibility of cross-sensitivity to other antibiotics should be considered.

Gastrointestinal: Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Some patients may develop bloody diarrhea. When this occurs, patients should contact their physician as soon as possible. Appropriate fluid and electrolyte management, protein supplements, and when appropriate, oral replacement therapy is necessary. In some instances of diarrhea associated with clindamycin, pseudomembranous colitis has been reported. Clindamycin and other antibiotics have been associated with a rare syndrome consisting of subacute colitis associated with a pseudomembranous colitis. The diagnosis of antibiotic-associated colitis should be made with caution in patients with diarrhea and a presumptive diagnosis of Clostridium difficile infection. Therefore, clindamycin should not be used in the treatment of meningitis.

PRECAUTIONS

Geriatric Use

Review of experience to date suggests that a subgroup of older people over 65 years of age with some severe illness may tolerate infection less well. When clindamycin is indicated in these patients, the dosage should be carefully monitored for changes in bowel frequency.

Clindamycin Palmitate Hydrochloride for Oral Solution should not be administered to patients who have had a previous allergic reaction to clindamycin or other lincomycin antibi- otics—particularly erythromycin. Superinfections may occur. If superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

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