

Dalacin C Sterile Solution

(clindamycin phosphate)

Dalacin C Capsules

(clindamycin hydrochloride)

Dalacin C Flavored Granules

(clindamycin palmitate)

Erratum

L. Ostergaard et al.: Evaluation of Urogenital *Chlamydia trachomatis* Infections by Cell Culture and the Polymerase Chain Reaction Using a Closed System (Volume 10, 1991, pages 1057-1061):

On page 1058, right hand-column, line 37 the sequence of the second primer should read:

5'GACCGGCCTCTAGCGCTGCG3'.

PRODUCT INFORMATION

INDICATIONS: Serious infections due to susceptible anaerobes; gram-positive aerobes, including streptococci, staphylococci, and pneumococci; and *Chlamydia trachomatis*. These include infections of the upper and lower respiratory tract, skin and soft tissue, and bone and joint; gynecologic and intra-abdominal infections (in conjunction with appropriate gram-negative aerobic coverage); cervicitis due to *C. trachomatis*; septicemia and endocarditis; dental infections; toxoplasmic encephalitis (when combined with pyrimethamine) in patients with AIDS who are intolerant to conventional treatment; and *Pneumocystis carinii* pneumonia in patients with AIDS who are intolerant to, or do not respond adequately to conventional treatment (may be combined with primaquine).

Concomitant administration of clindamycin phosphate with an aminoglycoside is effective in preventing peritonitis or intra-abdominal abscess after bowel perforation and bacterial contamination secondary to trauma.

Limited data from uncontrolled studies suggest that clindamycin is useful alternative therapy for the treatment of multidrug-resistant *Plasmodium falciparum* infection when given orally or parenterally at a dosage of 20 mg/kg/day for a minimum of 5 days, alone or combined with quinine or amodiaquine.

CONTRAINDICATIONS: Known hypersensitivity to clindamycin or lincomycin.

WARNINGS: DALACIN C Phosphate Sterile Solution contains benzyl alcohol, which has been associated with a fatal "Gasping Syndrome" in premature infants. Severe colitis, which may end fatally, has been reported with many antibiotics, including clindamycin. A toxin produced by *Clostridium difficile* is the major cause. The disease has a clinical spectrum from mild, watery diarrhea to severe, persistent diarrhea, leukocytosis, fever, and severe abdominal cramps possibly associated with passage of blood and mucus, which may progress to produce peritonitis, shock, and toxic megacolon. Diagnosis of antibiotic-associated colitis is usually made from clinical symptoms and can be substantiated endoscopically and confirmed by stool culture for *C. difficile* and stool assay for the toxin. Onset has occurred during antibiotic administration or 2 to 3 weeks after antibiotic cessation. Mild cases may respond to antibiotic discontinuation and colestipol or cholestyramine resins. Severe cases may require fluid, electrolyte, and protein supplementation and oral vancomycin 125 to 500 mg q6h for 7 to 10 days. Treat relapses with vancomycin. Alternative therapy for severe cases is oral bacitracin 25,000 units qid for 7 to 10 days. Avoid drugs that cause bowel stasis, eg, Lomotil. Antibiotic-associated colitis and diarrhea occur more frequently and may be more severe in patients who are elderly (>60 y) or debilitated, or both.

PRECAUTIONS: DALACIN C should be used with caution in patients with a history of GI disease, particularly colitis; should not be used to treat meningitis because it does not adequately penetrate cerebrospinal fluid; should be infused over 10 to 60 minutes and not given undiluted as a bolus. Monitor liver and kidney function during prolonged therapy. Nonsusceptible organisms, particularly yeasts, may overgrow. Clindamycin and erythromycin should not be administered concurrently because of antagonism. Use with caution in patients receiving neuromuscular blockers. Safety in pregnancy has not been established. Drug levels can be measured in breast milk. Use with caution in atopic individuals. Dosage reduction is not necessary in patients with renal or liver disease. Perform liver and kidney function tests if therapy is prolonged.

ADVERSE REACTIONS

Gastrointestinal – Abdominal pain, nausea, vomiting, and diarrhea (see Warnings). Esophagitis with oral preparations. **Hypersensitivity Reactions** – Maculopapular rash and urticaria; morbilliformlike skin rashes, erythema multiforme sometimes resembling Stevens-Johnson syndrome, and a few cases of anaphylactoid reactions. **Liver** – Jaundice and abnormalities in liver function tests. **Skin and mucous membranes** – Pruritus; vaginitis; and, rarely, exfoliative and vesiculobullous dermatitis. **Hematopoietic** – Transient neutropenia (leukopenia) and eosinophilia; agranulocytosis and thrombocytopenia; however, no direct etiologic relationship could be established. **Cardiovascular** – Rarely, cardiopulmonary arrest and hypotension following too rapid IV infusion. **Local reactions** – Local irritation, pain, abscess formation with IM injection; thrombophlebitis with IV injection.

DOSAGE RECOMMENDATIONS

DALACIN C Phosphate Sterile Solution (IM or IV): Adults: For intra-abdominal, female pelvic, or other complicated or serious infections, 2,400 to 2,700 mg/day in two, three, or four equal doses. Less complicated infections, 1,200 to 1,800 mg/day in three or four equal doses. Doses up to 4,800 mg/day have been used successfully. Single IM doses above 600 mg are not recommended. **Children over 1 month old:** 20 to 40 mg/kg/day in three or four equal doses. **Neonates (<1 month):** 15 to 20 mg/kg/day in three or four equal doses.

DALACIN C Capsules and Flavored Granules: Adults: 150 to 450 mg q6h. **Children over 1 month old:** 8 to 25 mg/kg/day in three or four equal doses. **Children weighing 10 kg or less:** 37.5 mg tid is the minimum dose.

β -Hemolytic streptococcal infections should be treated for at least 10 days.

Pelvic inflammatory disease – inpatient treatment: DALACIN C Phosphate Sterile Solution 900 mg (IV) q8h plus an appropriate gram-negative aerobic antibiotic for at least 4 days and at least 48 hours after patient improves. Continue with DALACIN C Capsules 450 mg q6h to complete 10 to 14 days total therapy.

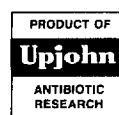
Cervicitis due to *C. trachomatis*: DALACIN C Capsules 450 mg q6h for 10 to 14 days⁶.

Toxoplasmic encephalitis in patients with AIDS: Clindamycin phosphate IV or oral clindamycin hydrochloride 600 to 1,200 mg q6h for 2 weeks followed by 300 to 600 mg by mouth q6h. Usual total duration of therapy is 8 to 10 weeks. Combine with oral pyrimethamine, 25 to 75 mg/day for 8 to 10 weeks. Folic acid 10 to 20 mg/day should be given with higher doses of pyrimethamine.

***P. carinii* pneumonia in patients with AIDS:** Clindamycin phosphate (IV) 600 to 900 mg q6h or 900 mg IV q8h or clindamycin hydrochloride 300 to 450 mg q6h for 21 days. Combine with oral primaquine 15 to 30 mg/day for 21 days.

Dilution and infusion rates: Clindamycin concentration in diluent should not exceed 18 mg/mL, and infusion rates should not exceed 30 mg/minute. No more than 1,200 mg should be infused in a single 1-hour infusion.

Incompatibility: The following drugs are physically incompatible with DALACIN C Phosphate Sterile Solution: ampicillin, phenytoin sodium, barbiturates, aminopylline, calcium gluconate, and magnesium sulfate.



REGISTERED TRADEMARK: DALACIN C
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