AVOCIN® Vaginal cream

Clindamycin 20mg/g (as clindamycin phosphate)

- The efficient treatment for bacterial vaginosis
- Superior clinical cure rate
- Higher patient compliance
- Cost effective

CONTRAINDICATIONS*

AVOCIN VAGINAL CREAM (clindamycin vaginal cream (as clindamycin phosphate)) is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin, lincomycin or any components of the cream (see DOSAGE FORMS, COMPOSITION AND PACKAGING).

AVOCIN VAGINAL CREAM is also contraindicated in individuals with a history of inflammatory bowel disease (including regional enteritis and ulcerative colitis), or a history of antibiotic - associated colitis (including pseudomembranous colitis). WARNINGS AND PRECAUTIONS

General Clindamycin should be prescribed with caution in atopic individuals. Cross resistance has been demonstrated between clindamycin and lincomycin. AVOCIN VAGINAL CREAM (clindamycin vaginal cream (as clindamycin phosphate)) is for intravaginal use only. AVOCIN VAGINAL CREAM contains ingredients that will cause burning and irritation of the eye. In the event of accidental contact with the eye, rinse the eye with copious amounts of cool tap water.

The patient should be instructed not to engage in vaginal intercourse or use other vaginal products (such as tampons or douches) during treatment with AVOCIN VAGINAL CREAM. The patient should be advised that this cream contains mineral oil. Mineral oil may weaken latex or rubber products such as condoms or vaginal contraceptive diaphragms; and therefore, use of such products within 72 hours following treatment with AVOCIN VAGINAL CREAM is not recommended.

In menstruating patients, treatment should be delayed until menstruation is completed. Vaginally applied clindamycin phosphate contained in AVOCIN VAGINAL CREAM could be absorbed in sufficient amounts to produce systemic effects. Approximately 4 mg of an administered dose of 100 mg clindamycin (as clindamycin phosphate) is systemically absorbed following vaginal administration (see ACTION AND CLINICAL PHARMACOLOGY). Use of clindamycin with other drugs may lead to drug-drug interactions (see DRUG INTERACTIONS).

Gastrointestinal*

Clostridium difficile-associated disease: Use of the topical formulation of clindamycin results in systemic absorption of 4% of the clindamycin dose. Clostridium difficile-associated disease (CDAD) has been reported with use of many antibacterial agents, including Clindamycin Vaginal Cream. CDAD may range in severity from mild diarrhea to fatal colitis. It is important to consider this diagnosis in patients who present with diarrhea, or symptoms of colitis, pseudomembranous colitis, toxic megacolon, or perforation of colon subsequent to the administration of any antibacterial agent. CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

Treatment with antibacterial agents may alter the normal flora of the colon and may permit overgrowth of Clostridium difficile. C. difficile produces toxins A and B, which contribute to the development of CDAD. CDAD may cause significant morbidity and mortality. If the diagnosis of CDAD is suspected or confirmed, appropriate therapeutic measures should be initiated. Mild cases of CDAD usually respond to discontinuation of antibacterial agents not directed against Clostridium difficile. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial agent clinically effective against Clostridium difficile. CDAD can be refractory to antimicrobial therapy. Surgical evaluation should be instituted as clinically indicated, as surgical intervention may be required in certain severe cases (see ADVERSE REACTIONS). Susceptibility/Resistance Prescribing AVOCIN VAGINAL CREAM in the absence of a proven or strongly suspected
bacterial infection is unlikely to provide benefit to the patient and risks the development of drugresistant bacteria.

Special Populations*

Pregnant Women: AVOCIN VAGINAL CREAM should not be used during pregnancy unless clearly needed and unless the expected benefits to the mother outweigh any potential risks to the fetus. There are no adequate and well-controlled studies in pregnant women during their first trimester. AVOCIN VAGINAL CREAM has been studied in pregnant women during the second trimester.
In women treated for seven days, abnormal labor was reported in 1.1% of patients who received AVOCIN VAGINAL CREAM compared with 0% of women treated for three days and 0.5% of women who received placebo for 7 days.

Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin ranging from 20 to 600 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus, except at doses that caused maternal toxicity. In one mouse strain, cleft palates were observed in treated fetuses; this response was not produced in other mouse strains or in other species, and therefore may be a strain specific effect. Animal reproduction studies are not always predictive of human response.

Nursing Women: It is not known if clindamycin is excreted in breast milk following the use of vaginally-administered clindamycin phosphate. However, orally and parenterally-administered

* Reference (Avocin PIL)

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The efficient treatment for
BACTERIAL VAGINOSIS

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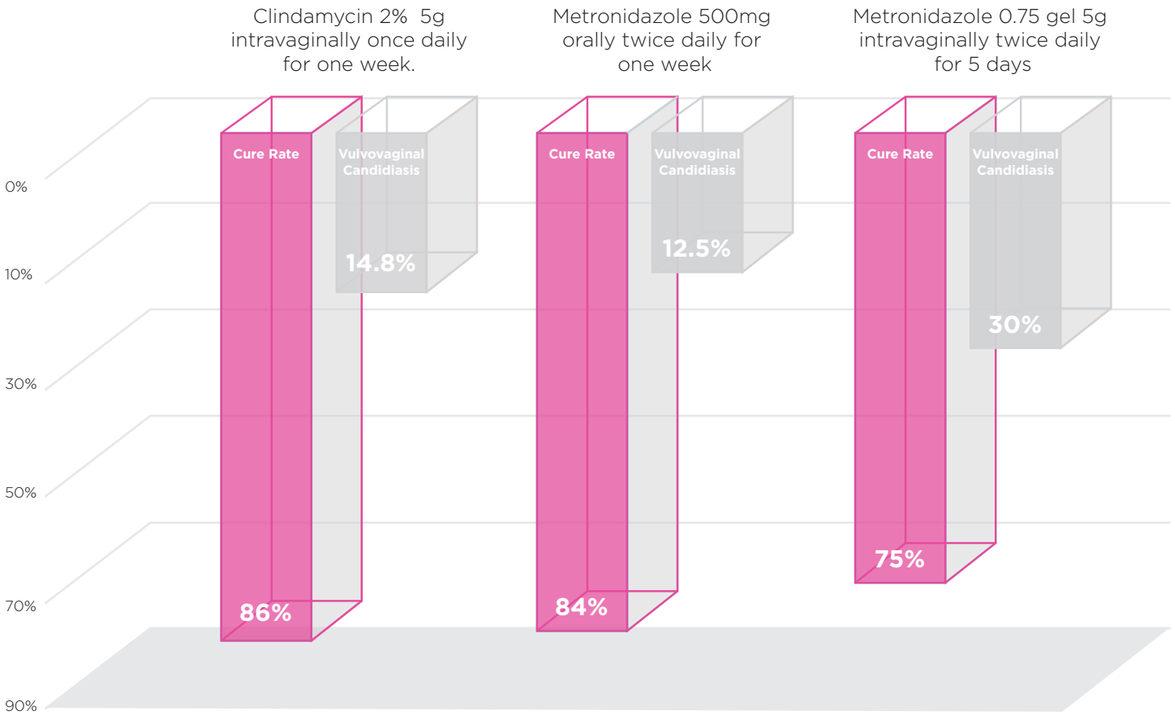
Avalon Pharma

AVOCIN® 2% Vaginal cream

Clindamycin 20mg/g (as clindamycin phosphate)

The efficient treatment for bacterial vaginosis

Superior clinical cure rate[1]



One hundred one women in whom bacterial vaginosis was diagnosed by standard criteria were randomly assigned to receive: oral metronidazole 500 mg twice daily for 1 week, 0.75% metronidazole vaginal gel 5 g twice daily for 5 days, or 2% clindamycin vaginal cream 5 g once daily for 7 days. Women with coexisting vulvovaginal candidiasis or vaginal trichomoniasis were excluded. Tests of cure by vaginal saline wet prep and potassium hydroxide microscopic examinations, Gram's stain, pH and DNA probe tests for Gardnerella vaginalis and Candida species were scheduled 7 to 14 days following treatment.

Avocin 2% (Clindamycin) vaginal cream shows higher efficacy in treatment of bacterial vaginosis incomparison to Metronidazole **(Orally or Vaginal)**[1]

(1) Ferris DG,et al. Treatment of bacterial vaginosis: comparison of oral metronidazole, metronidazole vaginal gel and clindamycin vaginal cream. J Fam Pract 1995; 41:443 -

AVOCIN® 2% Vaginal cream

Clindamycin 20mg/g (as clindamycin phosphate)

The efficient treatment for bacterial vaginosis

Higher patient compliance[1]

No Gastro intestinal symptoms ▶ **Higher patient compliance** ◀ Once daily application

Dosage & administration

One applicatorful (5g) of Avocin vaginal cream intravaginally at bedtime for seven consecutive nights.

(1) Ferris DG,et al. Treatment of bacterial vaginosis: comparison of oral metronidazole, metronidazole vaginal gel and clindamycin vaginal cream. J Fam Pract 1995; 41:443 -