

INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY

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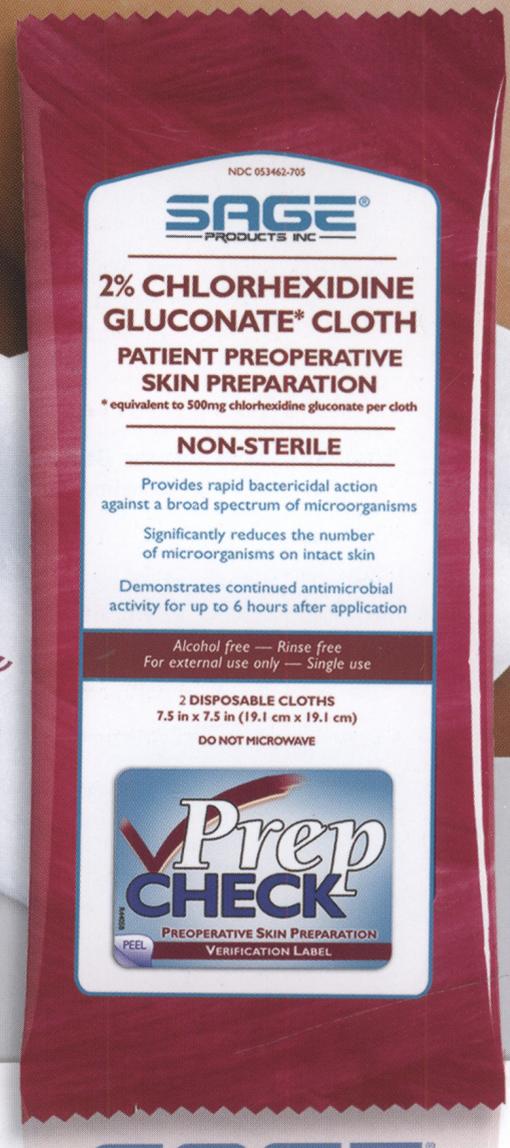
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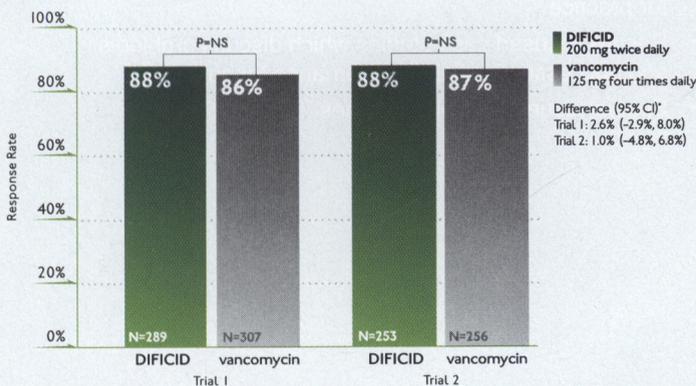


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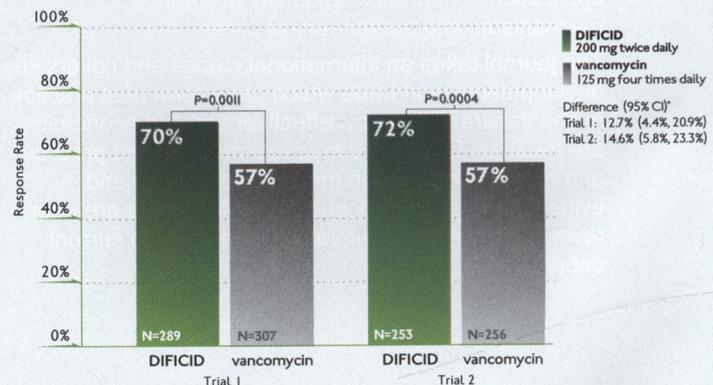
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➤ **Comparable clinical response rate at the end of 10-day treatment versus vancomycin (primary endpoint)¹**



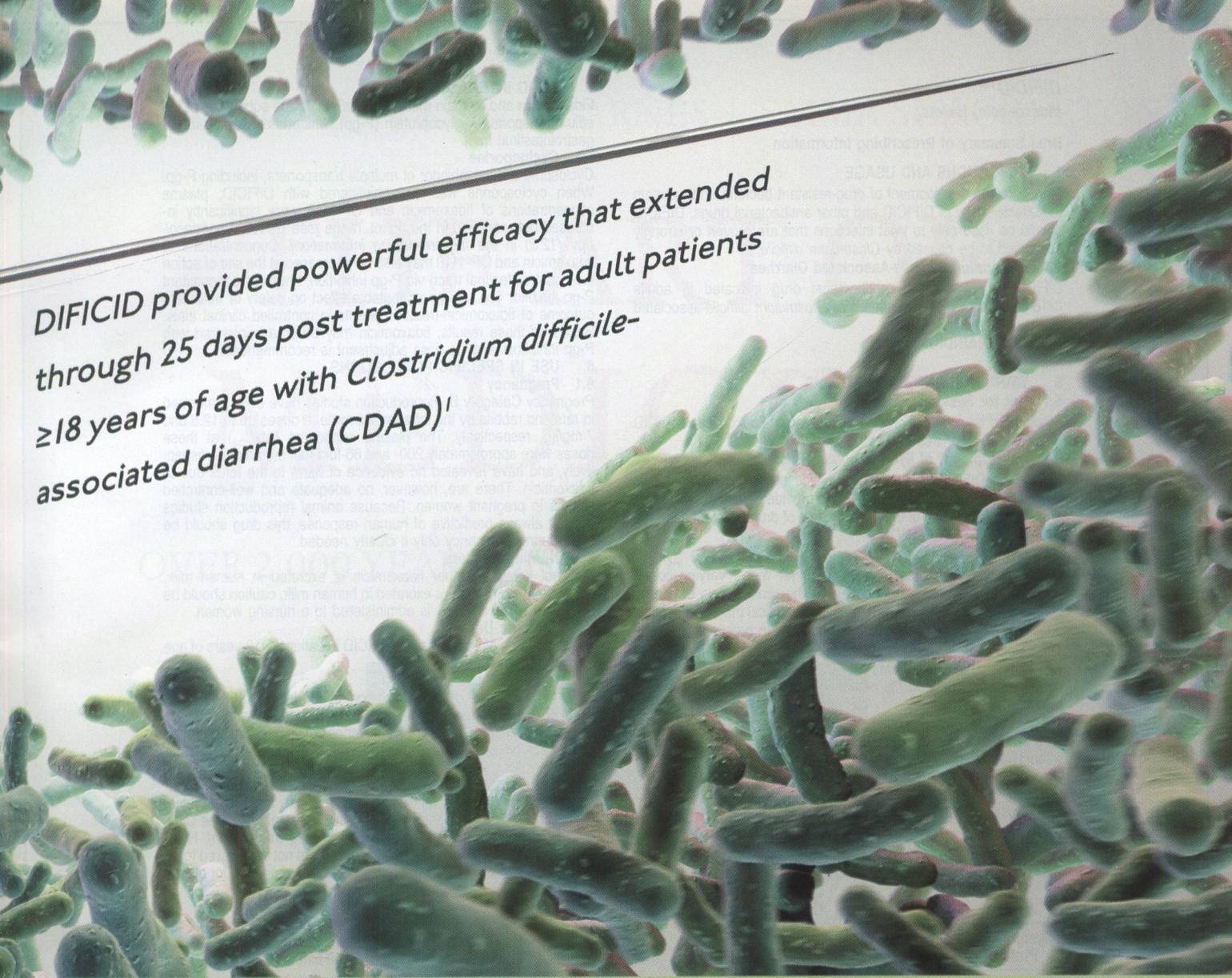
➤ **Superior sustained response rate through 25 days beyond the end of treatment versus vancomycin¹**



➤ Similar rates of clinical response at the end of treatment and proven or suspected CDAD during the follow-up period were seen in DIFICID-treated and vancomycin-treated patients infected with a BI isolate. However, DIFICID did not demonstrate superiority in sustained clinical response compared with vancomycin in these patients¹

➤ Sustained response rate was an additional efficacy endpoint defined as clinical response at the end of treatment and survival without proven or suspected CDAD recurrence through 25 days beyond the end of treatment¹

¹Confidence interval was derived using Wilson's score method. Approximately 5% to 9% of the data in each trial and treatment arm were missing sustained response data and were imputed using a multiple imputation method.¹



DIFICID provided powerful efficacy that extended through 25 days post treatment for adult patients ≥ 18 years of age with *Clostridium difficile*-associated diarrhea (CDAD)¹

STUDY DESCRIPTION: Two phase 3, randomized, double-blind, non-inferiority studies (N=1105) comparing the efficacy and safety of oral DIFICID 200 mg twice daily versus oral vancomycin 125 mg four times daily for 10 days in the treatment of adults (aged ≥ 18 years) with CDAD (defined by >3 unformed bowel movements in the 24 hours before randomization and presence of either *C. difficile* toxin A or B in the stool within 48 hours of randomization). Enrolled patients received no more than 24 hours of pretreatment with vancomycin or metronidazole and had either no prior CDAD history or only one prior CDAD episode in the past 3 months. Subjects with life-threatening/fulminant infection, hypotension, septic shock, peritoneal signs, significant dehydration, or toxic megacolon were excluded.¹

Indications and Usage

- DIFICID is a macrolide antibacterial drug indicated in adults ≥ 18 years of age for treatment of *Clostridium difficile*-associated diarrhea
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of DIFICID and other antibacterial drugs, DIFICID should be used only to treat infections that are proven or strongly suspected to be caused by *Clostridium difficile*

Important Safety Information

- DIFICID should not be used for systemic infections
- Only use DIFICID for infection proven or strongly suspected to be caused by *C. difficile*. Prescribing DIFICID in the absence of a proven or strongly suspected *C. difficile* infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria
- The most common adverse reactions are nausea (11%), vomiting (7%), abdominal pain (6%), gastrointestinal hemorrhage (4%), anemia (2%), and neutropenia (2%)

Please see brief summary of full prescribing information for DIFICID on adjacent page.

For more information, please visit DIFICID.com

Reference: 1. DIFICID [package insert]. San Diego, CA: Optimer Pharmaceuticals, Inc; May 2011.



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DIFICID[™]
(fidaxomicin) tablets
200mg

FIGHT FORWARD

DIFICID™ (fidaxomicin) tablets

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DIFICID and other antibacterial drugs, DIFICID should be used only to treat infections that are proven or strongly suspected to be caused by *Clostridium difficile*.

1.1 *Clostridium difficile*-Associated Diarrhea

DIFICID is a macrolide antibacterial drug indicated in adults (≥18 years of age) for treatment of *Clostridium difficile*-associated diarrhea (CDAD).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Not for Systemic Infections

Since there is minimal systemic absorption of fidaxomicin, DIFICID is not effective for treatment of systemic infections.

5.2 Development of Drug Resistant Bacteria

Prescribing DIFICID in the absence of a proven or strongly suspected *C. difficile* infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of any other drug and may not reflect the rates observed in practice.

The safety of DIFICID 200 mg tablets taken twice a day for 10 days was evaluated in 564 patients with CDAD in two active-comparator controlled trials with 86.7% of patients receiving a full course of treatment.

Thirty-three patients receiving DIFICID (5.9%) withdrew from trials as a result of adverse reactions (AR). The types of AR resulting in withdrawal from the study varied considerably. Vomiting was the primary adverse reaction leading to discontinuation of dosing; this occurred at an incidence of 0.5% in both the fidaxomicin and vancomycin patients in Phase 3 studies.

Table 1. Selected Adverse Reactions with an Incidence of ≥2% Reported in DIFICID Patients in Controlled Trials

	DIFICID (N=564)	Vancomycin (N=583)
System Organ Class Preferred Term	n (%)	n (%)
Blood and Lymphatic System Disorders		
Anemia	14 (2%)	12 (2%)
Neutropenia	14 (2%)	6 (1%)
Gastrointestinal Disorders		
Nausea	62 (11%)	66 (11%)
Vomiting	41 (7%)	37 (6%)
Abdominal Pain	33 (6%)	23 (4%)
Gastrointestinal Hemorrhage	20 (4%)	12 (2%)

The following adverse reactions were reported in <2% of patients taking DIFICID tablets in controlled trials:

Gastrointestinal Disorders: abdominal distension, abdominal tenderness, dyspepsia, dysphagia, flatulence, intestinal obstruction, megacolon

Investigations: increased blood alkaline phosphatase, decreased blood bicarbonate, increased hepatic enzymes, decreased platelet count

Metabolism and Nutrition Disorders: hyperglycemia, metabolic acidosis

Skin and Subcutaneous Tissue Disorders: drug eruption, pruritus, rash

7 DRUG INTERACTIONS

Fidaxomicin and its main metabolite, OP-1118, are substrates of the efflux transporter, P-glycoprotein (P-gp), which is expressed in the gastrointestinal tract.

7.1 Cyclosporine

Cyclosporine is an inhibitor of multiple transporters, including P-gp. When cyclosporine was co-administered with DIFICID, plasma concentrations of fidaxomicin and OP-1118 were significantly increased but remained in the ng/mL range [see *Clinical Pharmacology (12.3) in the full prescribing information*]. Concentrations of fidaxomicin and OP-1118 may also be decreased at the site of action (i.e., gastrointestinal tract) via P-gp inhibition; however, concomitant P-gp inhibitor use had no attributable effect on safety or treatment outcome of fidaxomicin-treated patients in controlled clinical trials. Based on these results, fidaxomicin may be co-administered with P-gp inhibitors and no dose adjustment is recommended.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B. Reproduction studies have been performed in rats and rabbits by the intravenous route at doses up to 12.6 and 7 mg/kg, respectively. The plasma exposures (AUC₀₋₂₄) at these doses were approximately 200- and 66-fold that in humans, respectively, and have revealed no evidence of harm to the fetus due to fidaxomicin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

8.3 Nursing Mothers

It is not known whether fidaxomicin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DIFICID is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of DIFICID in patients <18 years of age have not been established.

8.5 Geriatric Use

Of the total number of patients in controlled trials of DIFICID, 50% were 65 years of age and over, while 31% were 75 and over. No overall differences in safety or effectiveness of fidaxomicin compared to vancomycin were observed between these subjects and younger subjects.

In controlled trials, elderly patients (≥65 years of age) had higher plasma concentrations of fidaxomicin and its main metabolite, OP-1118, versus non-elderly patients (<65 years of age) [see *Clinical Pharmacology (12.3) in the full prescribing information*]. However, greater exposures in elderly patients were not considered to be clinically significant. No dose adjustment is recommended for elderly patients.

10 OVERDOSAGE

No cases of acute overdose have been reported in humans. No drug-related adverse effects were seen in dogs dosed with fidaxomicin tablets at 9600 mg/day (over 100 times the human dose, scaled by weight) for 3 months.

Manufactured for Optimer Pharmaceuticals, Inc., San Diego CA 92121 by Patheon, Inc.

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Product protected by US Patent Nos. 7,378,508; 7,507,564; 7,863,249; and 7,906,489

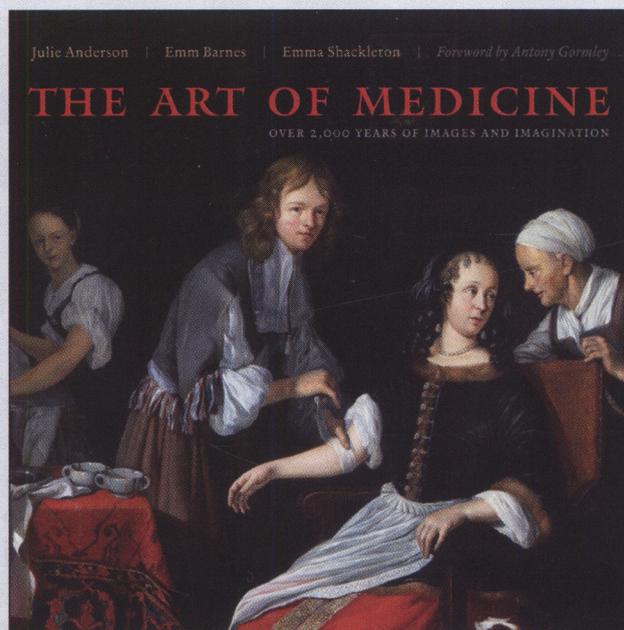
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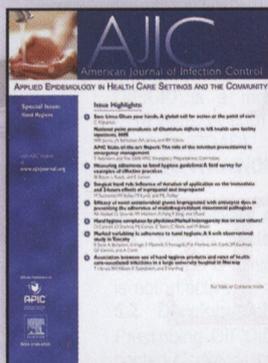


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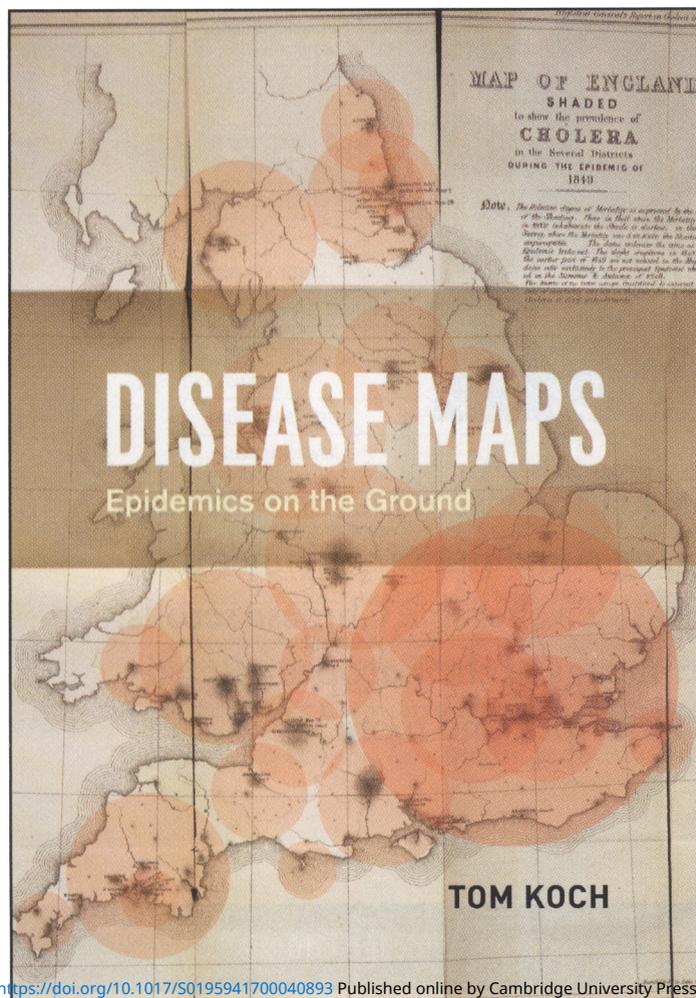
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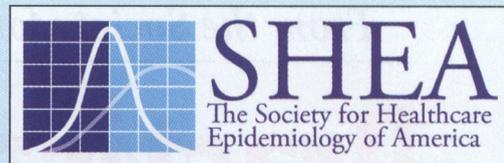
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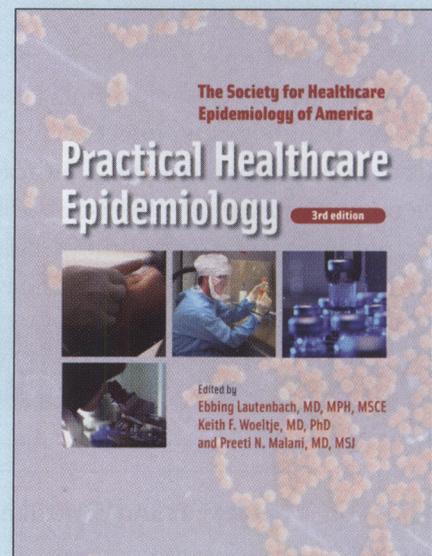
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