

# INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY

VOLUME 32, NUMBER 11

NOVEMBER 2011

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# INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY

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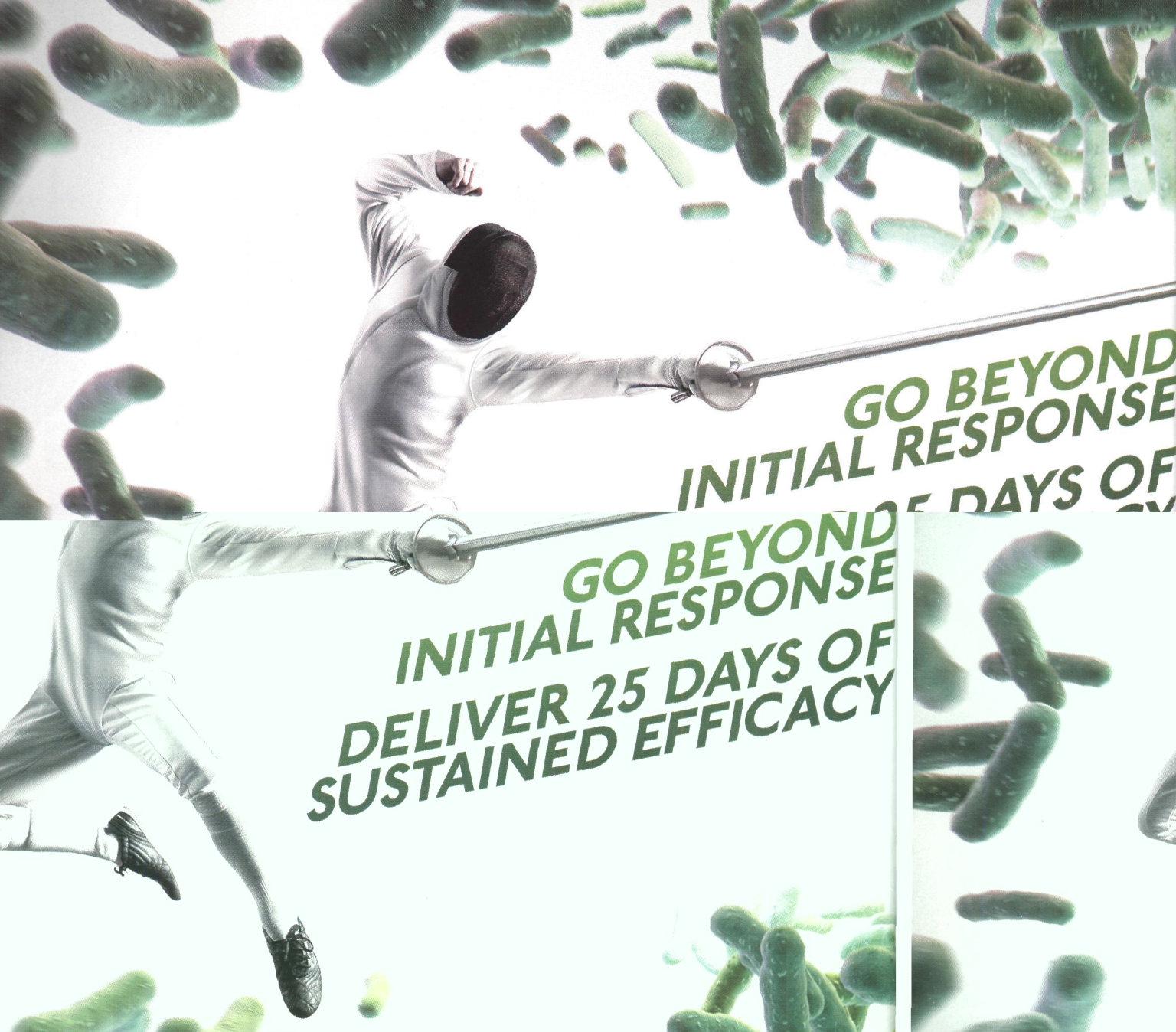
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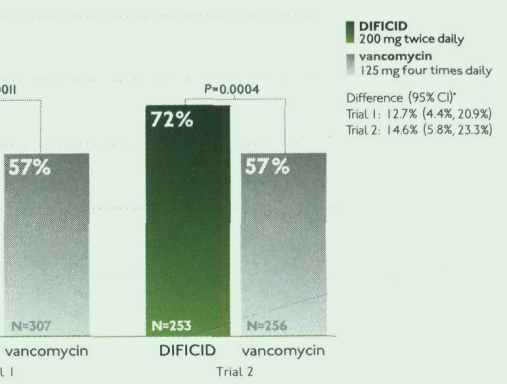
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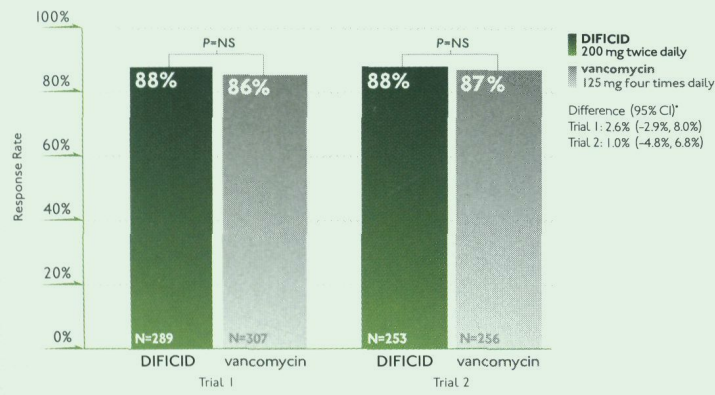


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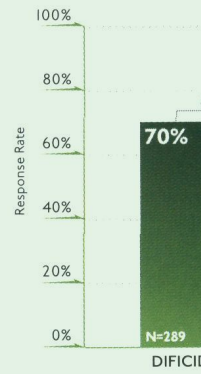
...and the end of  
versus vancomycin<sup>1</sup>



...vancomycin (primary endpoint)<sup>1</sup>



...treatment



...follow-up period were seen in DIFICID-treated  
...superiority in sustained clinical response compared

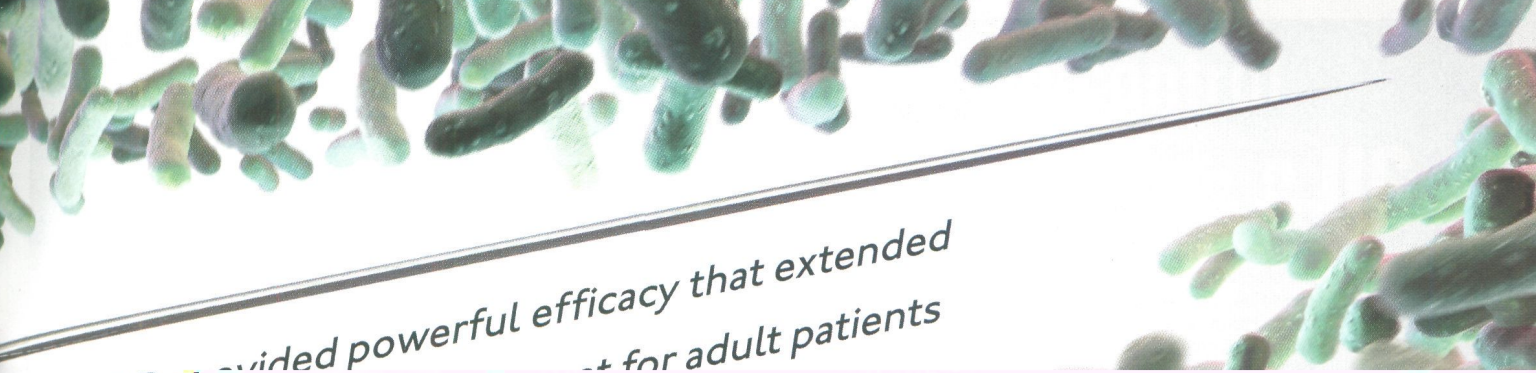
...treatment and survival without proven or

...were missing sustained response data

- Similar rates of clinical response at the end of treatment and proven or suspected CDAD during treatment and vancomycin-treated patients infected with a BI isolate. However, DIFICID did not demonstrate superiority with vancomycin in these patients<sup>1</sup>
- Sustained response rate was an additional efficacy endpoint defined as clinical response at the end of treatment and without proven or suspected CDAD recurrence through 25 days beyond the end of treatment<sup>1</sup>

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





...provided powerful efficacy that extended  
... for adult patients

## PROVEN EFFICACY FOR TREATING CLOSTRIDIUM DIFFICILE (CDI)

### 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](http://DIFICID.com)

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

PTIMER

**DIFICID**  
(fidaxomicin)

FIGHT FORWARD

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## 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		

#### 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 (AUC<sub>0-24</sub>) 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

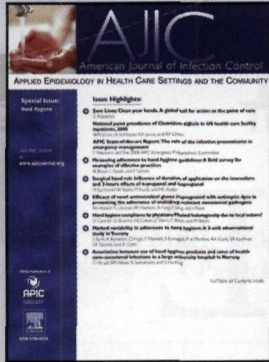
No cases of acute overdose have been reported in humans. No drug-related adverse effects were seen in dogs dosed with fidaxomicin tablets at 9600 mg/day (over 100 times the human dose, scaled by weight) for 3 months.

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

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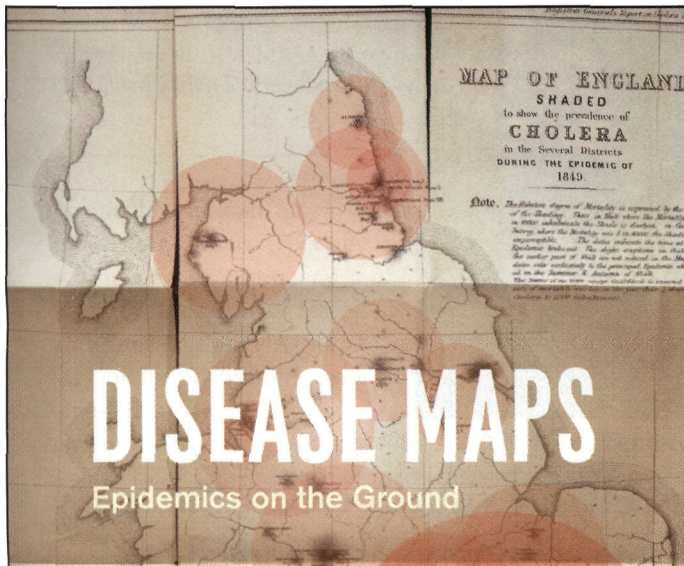
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