INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY

VOLUME 32, NUMBER 11 NOVEMBER 2011

ORIGINAL ARTICLES

REVIEW ARTICLE

CONCISE COMMUNICATIONS

CONTENTS CONTINUED INSIDE

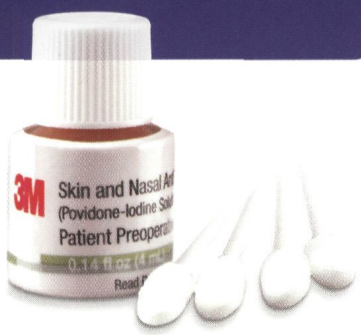
SHEA The Society for Healthcare Epidemiology of America

THE OFFICIAL JOURNAL OF THE SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA

THE UNIVERSITY OF CHICAGO PRESS

https://doi.org/10.1017/S0195941711001... Published online by Cambridge University Press

I'm Cardiac Joe.
I'm in charge of infection control....really?



3M™ Skin and Nasal Antiseptic
(Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP)
Patient Preoperative Skin Preparation

Meet Joe. He's heading into heart surgery and he's not always good at following the doctor's orders. Joe ate a few hours ago and forgot to use the shower product his doctor provided. He's got bacteria in his nares and his noncompliance is about to wreak havoc on your infection control measures.

Some patients just don't understand the negative impact they can have on their procedural outcomes. Don't give control to Cardiac Joe when you can take charge with 3M™ Skin and Nasal Antiseptic. Administer it one hour before surgery to decrease bacteria in the nares[1]. It's easy to apply and is specially formulated to be non-irritating[2] and drip resistant.

Your first line of defense against surgical site infections occurs in the pre-operative environment. Learn how 3M™ Skin and Nasal Antiseptic can help you reduce bacteria in the nares, which may lower your risk of SSIs. Visit **www.3M.com/TakeControl** for a free product sample.

Don't let Cardiac Joe, or his nose, blow your infection control program. Take back the control.

1. 3M Skin and Nasal Antiseptic Safety and Efficacy Data, I2MS Study-05-011100
2. 3M Study 05-011017

3M Infection Prevention Solutions
Innovation On A Mission

© 3M 2011. All rights reserved.
70-2010-8379-0

3M

https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press

INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY

VOLUME 32, NUMBER 11 NOVEMBER 2011

CONTENTS CONTINUED FROM COVER

https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

http://www.journals.uchicago.edu/ICHE

An Official Publication of the Society for Healthcare Epidemiology of America

EDITOR
Suzanne F. Bradley, MD • Ann Arbor, MI

DEPUTY EDITOR
Carol A. Kauffman, MD • Ann Arbor, MI

SENIOR ASSOCIATE EDITORS
C. Glen Mayhall, MD • Galveston, TX
Gina Pugliese, RN, MS • Chicago, IL
William Schaffner, MD • Nashville, TN

ASSOCIATE EDITORS
Ebbing Lautenbach, MD, MPH • Philadelphia, PA
Preeti N. Malani, MD, MSJ • Ann Arbor, MI
David Weber, MD, MPH • Chapel Hill, NC

STATISTICS CONSULTANT
Rodney L. Dunn, MS • Ann Arbor, MI

SECTION EDITOR FOR GUIDELINES, POSITION PAPERS, AND INVITED REVIEWS
Carol Chenoweth, MD • Ann Arbor, MI

MANAGING EDITOR
Rob Blixt • Chicago, IL

PAST EDITORS
Infection Control
Richard P. Wenzel, MD, 1980–1990 (vols. 1–11)
Infection Control and Hospital Epidemiology
Richard P. Wenzel, MD, 1991–1992 (vols. 12 and 13)
Michael D. Decker, MD, 1993–2001 (vols. 14–22)
Barry M. Farr, MD, 2002–2004 (vols. 23–25)
William R. Jarvis, MD, 2005–2006 (vols. 26 and 27)

EDITORIAL ADVISORY BOARD

Miriam Alter, PhD, MD • Atlanta, GA
Anucha Apisarnthanarak, MD • Pratumthani, Thailand
Lennox Archibald, MD, FRCP • Alachua, FL
Hilary Babcock, MD • St. Louis, MO
Elise M. Beltrami, MD, MPH • Decatur, GA
David Birnbaum, PhD, MPH • Sidney, BC
Christian Brun-Buisson, MD • Creteil, France
John P. Burke, MD • Salt Lake City, UT
David P. Calfee, MD, MS • New York, NY
Yehuda Carmeli, MD, MPH • Tel Aviv, Israel
Sara E. Cosgrove, MD, MS • Baltimore, MD
Donald E. Craven, MD • Burlington, MA
Burke A. Cunha, MD • Mineola, NY
Erika D'Agata, MD, MPH • Boston, MA
Patch Dellinger, MD • Seattle, WA
Daniel Diekema, MD • Iowa City, IA
Charles E. Edmiston, Jr., PhD • Milwaukee, WI
Theodore C. Eickhoff, MD • Denver, CO
Martin S. Favero, PhD • Irvine, CA
Jon P. Furuno, PhD • Baltimore, MD
Petra Gastmeier, MD • Hanover, Germany
Dale N. Gerding, MD • Hines, IL
Donald A. Goldmann, MD • Boston, MA
Donna Haiduven, RN, PhD, CIC • Tampa, FL
Anthony D. Harris, MD, MPH • Baltimore, MD
David K. Henderson, MD • Bethesda, MD
Loreen A. Herwaldt, MD • Iowa City, IA
Peter N. R. Heseltine, MD • San Juan, CA
Karen Hoffmann, RN, CIC, MS • Chapel Hill, NC
Janine Jagger, MPH, PhD • Charlottesville, VA
John A. Jernigan, MD, MS • Atlanta, GA
James T. Lee, MD, PhD • St. Paul, MN
L. Clifford McDonald, MD • Atlanta, GA
Allison McGeer, MD • Toronto, ON
Leonard A. Mermel, DO, ScM • Providence, RI
Robert R. Muder, MD • Pittsburgh, PA
Carlene A. Muto, MD, MS • Pittsburgh, PA
Joseph M. Mylotte, MD, CIC • Buffalo, NY
David L. Paterson, MBBS, FRACP • Pittsburgh, PA
Jan Evans Patterson, MD • San Antonio, TX
Sindy M. Paul, MD • Yardley, PA
David A. Pegues, MD • Los Angeles, CA
Eli Perencevich, MD, MS • Baltimore, MD
Michael A. Pfaller, MD • Iowa City, IA
Didier Pittet, MD, MS • Geneva, Switzerland
Gina Pugliese, RN, MS • Chicago, IL
Isaam Raad, MD • Houston, TX
Jordi Rello, MD, PhD • Tarragona, Spain
Manfred L. Rotter, MD, DipBact • Vienna, Austria
Henning Rüden, MD • Berlin, Germany
William A. Rutala, PhD, MPH • Chapel Hill, NC
Lisa Saiman, MD, MPH • New York, NY
Sanjay Saint, MD, MPH • Ann Arbor, MI
William E. Scheckler, MD • Madison, WI
Lynne M. Sehulster, PhD • Atlanta, GA
John A. Sellick, DO • Amherst, NY
Kent Sepkowitz, MD • New York, NY
Samir Shah, MD, MSCE • Philadelphia, PA
Andrew E. Simor, MD • Toronto, ON
Philip W. Smith, MD • Omaha, NE
Denis W. Spelman, MD • Prahan, Victoria, Australia
Jeffrey R. Starke, MD • Houston, TX
Janet E. Stout, PhD • Pittsburgh, PA
Clyde Thornsberry, PhD • Franklin, TN
William Trick, MD • Chicago, IL
Antoni Trilla, MD, PhD • Barcelona, Spain
Robert A. Weinstein, MD • Chicago, IL
Andreas Widmer, MD, MS • Basel, Switzerland
Marcus Zervos, MD • Royal Oak, MI

Infection Control and Hospital Epidemiology (ISSN 0899-823X) is published monthly by the University of Chicago Press, 1427 E. 60th St., Chicago, IL 60637-2954 (http://www.journals.uchicago.edu/ICHE/). The editorial office is in Chicago, Illinois.

Editorial Office
Communications should be addressed to the Editor, *Infection Control and Hospital Epidemiology*, 1427 E. 60th St., Chicago, IL 60637-2954; (e-mail: iche@press.uchicago.edu; telephone: 773-702-2538, fax: 773-753-4247). Contributors should consult the Information for Authors, which is available at the journal's Web site.

Advertising
Please direct advertising inquiries to Paul Tucker, Breuning Nagle Associates, 59 Grove Street, New Canaan, CT 06840 (e-mail: paul@bna1.com; telephone: 847-669-1096, fax: 203-801-0011). Publication of an advertisement in *Infection Control and Hospital Epidemiology* does not imply endorsement of its claims by the Society for Healthcare Epidemiology of America, by the Editor, or by the University of Chicago. Correspondence regarding advertising should be addressed to the advertising office in Chicago.

Permissions
Articles may be copied or otherwise reused without permission only to the extent permitted by Sections 107 and 108 of the US Copyright Law. Permission to copy articles for personal, internal, classroom, or library use may be obtained from the Copyright Clearance Center (http://www.copyright.com). For all other uses, such as copying for general distribution, for advertising or promotional purposes, for creating new collective works, or for resale, please contact the Permissions Coordinator, Journals Division, University of Chicago Press, 1427 E. 60th St., Chicago, IL 60637 (e-mail: journalpermissions@press.uchicago.edu; fax: 773-834-3489). Articles in the public domain may be used without permission, but it is customary to contact the author.

Subscriptions
Individual subscription rates for 2012 are $191. Lower rates for fellows, residents, and students are available at http://www.journals.uchicago.edu/ICHE. Individuals have the option to order directly from the University of Chicago Press. Institutional print + electronic and e-only subscriptions are available through JSTOR's Current Scholarship Program and include unlimited online access; rates are tiered according to an institution's type and research output: $425 to $1,063 (print + electronic), $340 to $884 (e-only). Institutional print-only is $425. Additional taxes and/or postage for non-U.S. subscriptions may apply. Subscription agent for Japan: Kinokuniya Company, Ltd. Free or deeply discounted access is available in most developing nations through the Chicago Emerging Nations Initiative (http://www.journals.uchicago.edu/ceni/).

Please direct subscription inquries, requests for back issues, and address changes to Journals Division, University of Chicago Press, P.O. Box 37005, Chicago, IL 60637 (e-mail: subscriptions@press.uchicago.edu; telephone: 773-753-3347 or toll-free in the United States and Canada 877-705-1878; fax: 773-753-0811 or toll-free 877-705-1879).

Postmaster: Send address changes to *Infection Control and Hospital Epidemiology*, University of Chicago Press, P.O. Box 37005, Chicago, IL 60637-2954.

Periodicals postage paid at Chicago, Illinois, and at an additional mailing office.

Published by the University of Chicago Press, Chicago, Illinois. © 2011 by the Society for Healthcare Epidemiology of America. All rights reserved. This publication is printed on acid-free paper.

https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press

Emerald Journals

Clinical Governance

An International Journal

Clinical Governance: An International Journal aims to address the doubts, queries, triumphs and practical applications of introducing quality assurance mechanisms into the delivery of care.

The journal takes an international stance and covers key developments worldwide which can inform best practice in health care. Efficiency, effectiveness and economics are the main factors in the assessment of best practice and all are addressed in the research- audit- and evidence-based papers published. All papers are peer reviewed to ensure their validity and value to current debates.

The journal publishes:

- Research articles which illustrate clear implications for practice
- Results-focused case studies which discuss problems and successes in clinical governance techniques
- Special issues on topical themes

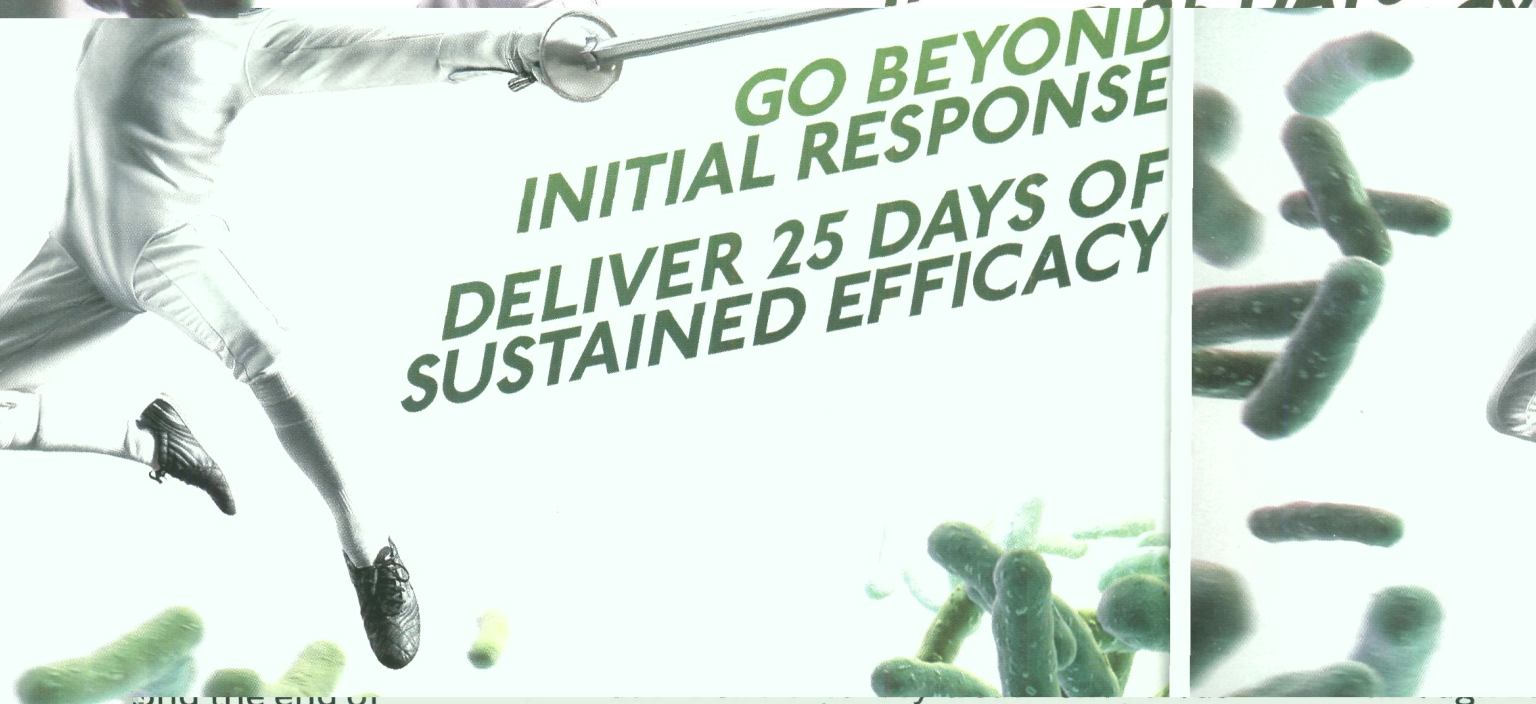
For more information please visit the homepage:
www.emeraldinsight.com/cgij.htm

To submit a paper visit:
http://mc.manuscriptcentral.com/cgij

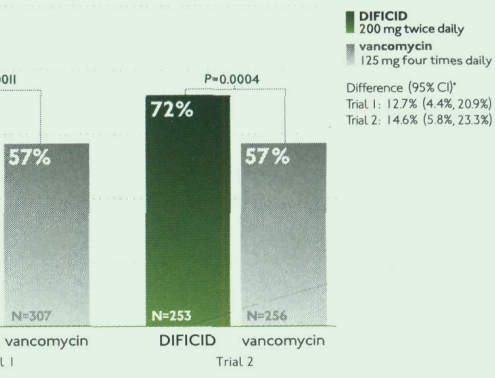
Emerald

Research you can use

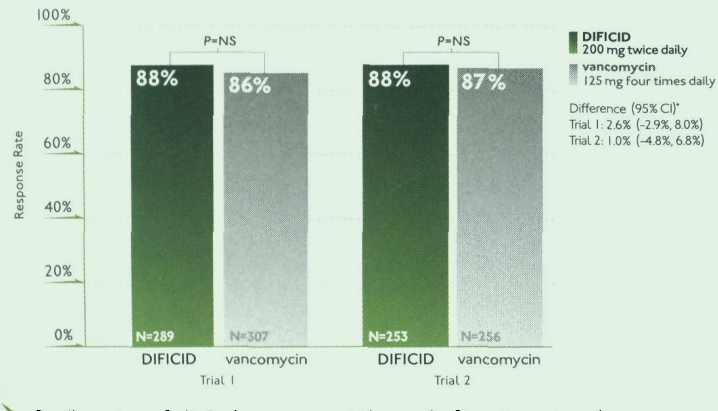
https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press



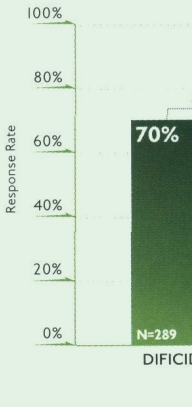
ersus vancomycin[1]



vancomycin (primary endpoint)[1]



treatment



ollow-up period were seen in DIFICID-treated
periority in sustained clinical response compared

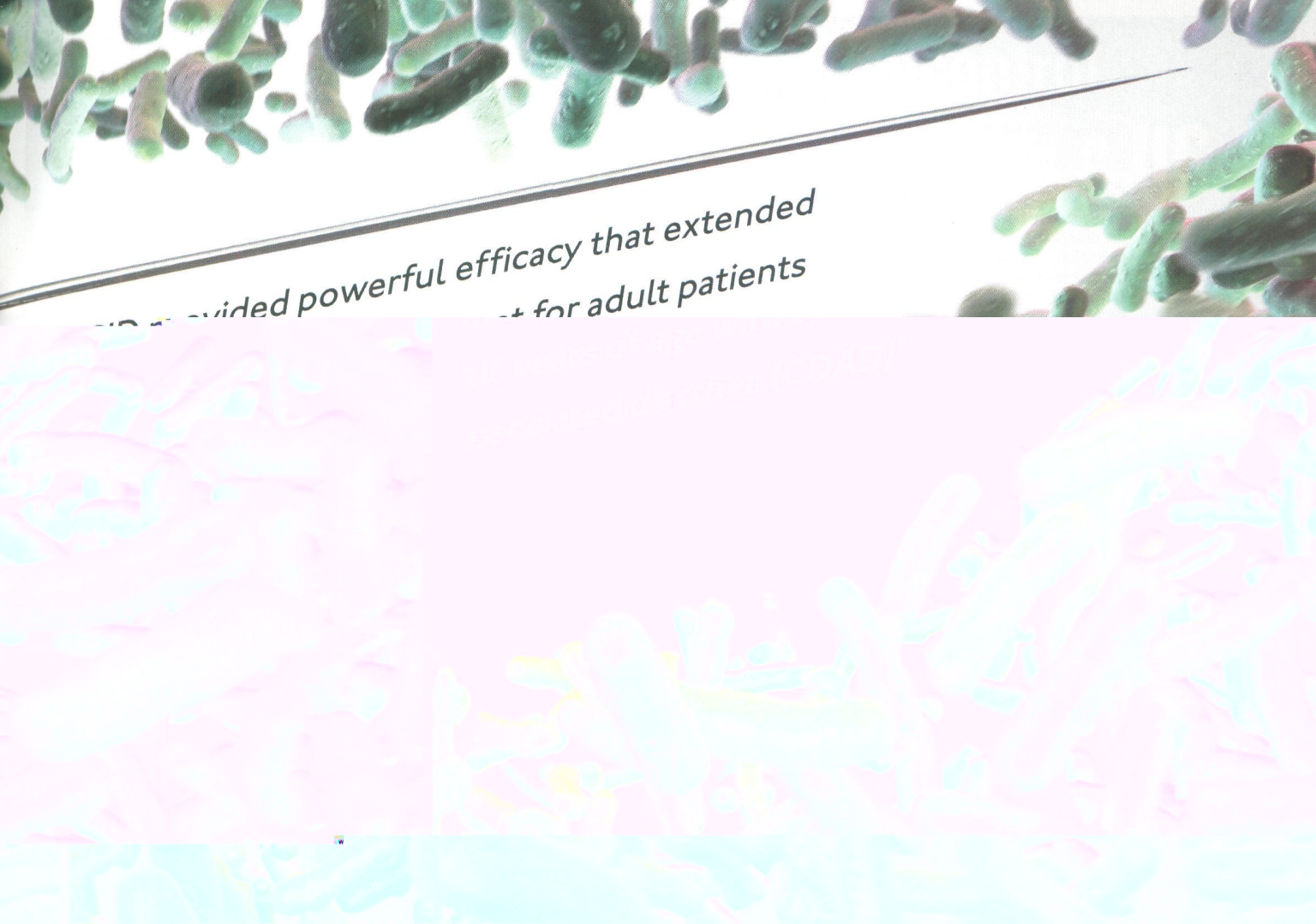
treatment and survival without proven or

- Similar rates of clinical response at the end of treatment and proven or suspected CDAD during th and vancomycin-treated patients infected with a BI isolate. However, DIFICID did not demonstrate with vancomycin in these patients[1]
- Sustained response rate was an additional efficacy endpoint defined as clinical response at the end suspected CDAD recurrence through 25 days beyond the end of treatment[1]

were missing sustained response data

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

https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press



Indication 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.

FIDELIO-1

DIFICID (fidaxomicin) 200 mg

RIGHT FORWARD

© 2011 Optimer Pharmaceuticals, Inc. San Diego, CA 92121 October 2011 DF_1102_0181

https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press

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_{0-t}) 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.

DIFICID™ is a trademark of Optimer Pharmaceuticals, Inc.

https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press

Find the latest in infection control research and practice information in AJIC

American Journal of Infection Control

EDITOR: **Elaine L. Larson, RN, PhD, FAAN, CIC**

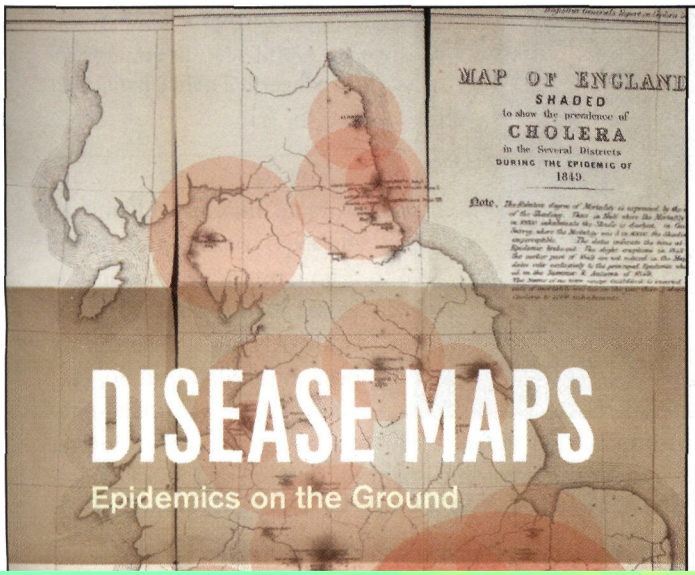
AJIC covers key topics and issues in infection control and epidemiology. Infection control professionals, including physicians, nurses, and epidemiologists, rely on **AJIC** for peer-reviewed articles covering clinical topics as well as original research. As the official publication of the *Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)*, **AJIC** is the foremost resource on infection control, epidemiology, infectious diseases, quality management, occupational health, and disease prevention. **AJIC** also publishes relevant infection control guidelines. **AJIC** is included in Index Medicus and CINAHL.

Official Publication of the Association for Professionals in Infection Control and Epidemiology, Inc.

Register at ajicjournal.org to receive free access to Tables of Contents and all article abstracts; free access to select full text articles; free e-alerts and search personalization, and more!

ELSEVIER

Submit your manuscript at: http://ees.elsevier.com/ajic/



FORTHCOMING IN MAY

"*Disease Maps* is an extraordinary visual and narrative treat. I have come to look forward to Tom Koch's books for the wonderful and unique way that he can synthesize data and present it visually and in the process tell us magnificent stories."

Dr. Abraham Verghese,
Stanford University School of Medicine

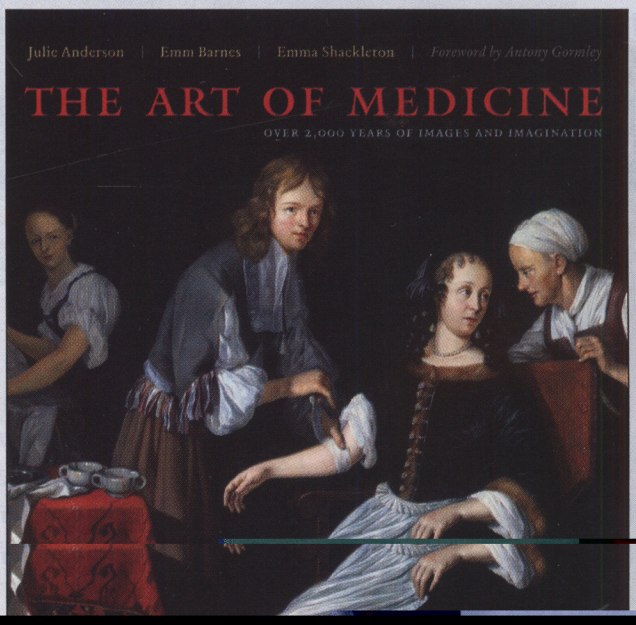
"This is a masterful book in conception and structure. It is also extremely well written. What we find on reading is an exquisite telling of the history of the medical science

https://doi.org/10.1017/S0195941700030034 Published online by Cambridge University Press

JULIE ANDERSON | EMM BARNES | EMMA SHACKLETON

THE ART OF MEDICINE

OVER 2,000 YEARS OF IMAGES AND IMAGINATION



https://doi.org/10.1017/S0195941700030034