

The Medical Letter®

On Drugs and Therapeutics

Published by The Medical Letter, Inc. • 1000 Main Street, New Rochelle, NY 10801 • A Nonprofit Publication

Volume 48 (Issue 1243)
September 11, 2006

www.medicalletter.org

IN BRIEF

Natalizumab (*Tysabri*) Returns

Soon after The Medical Letter first reviewed use of natalizumab (*Tysabri* — Biogen Idec and Elan) for treatment of relapsing forms of multiple sclerosis (MS) ([Med Lett Drugs Ther 2005; 47:13](#)), the drug was withdrawn from the market. The unpublished clinical trials that led to its approval by the FDA have since been published, and now the drug has been returned to the market with prescribing restrictions.

Natalizumab decreases the number of relapses and new brain lesions in patients with MS. It was withdrawn because progressive multifocal leukoencephalopathy (PML) occurred in 3 (of about 3000) patients being treated with the drug; two were taking the drug in combination with interferon beta for MS, and one was taking it with azathioprine for Crohn's disease. PML is an opportunistic infection of the brain, caused by reactivation of the JC virus in immunosuppressed patients, that often causes death or severe neurological disability. There is no treatment for PML.

The publication of the natalizumab clinical trials in MS provided information on the drug's effect on the progression of disability, which was not available when it was first reviewed here. In one study, combination therapy with natalizumab and interferon beta-1a for 2 years led to an estimated cumulative probability of progression of 23%, compared to 29% with interferon beta-1a alone ([RA Rudick et al. N Engl J Med 2006; 354:911](#)). In the second study, the estimated cumulative probability of progression over 2 years was 17% with natalizumab alone and 29% with placebo ([CH Polman et al. N Engl J Med 2006; 354:899](#)).

The Medical Letter®

On Drugs and Therapeutics

EDITOR: Mark Abramowicz, M.D.
DEPUTY EDITOR: Gianna Zuccotti, M.D., M.P.H., Weill Medical College of Cornell University
EDITOR, DRUG INFORMATION: Jean-Marie Pflomm, Pharm.D.
CONTRIBUTING EDITOR, DRUG INFORMATION: Nina H. Cheigh, Pharm.D.
ADVISORY BOARD:
Jules Hirsch, M.D., Rockefeller University
James D. Kenney, M.D., Yale University School of Medicine
Richard B. Kim, M.D., University of Western Ontario
Gerald L. Mandell, M.D., University of Virginia School of Medicine
Hans Meinertz, M.D., University Hospital, Copenhagen
Dan M. Roden, M.D., Vanderbilt University School of Medicine
F. Estelle R. Simons, M.D., University of Manitoba
Neal H. Steigbigel, M.D., New York University School of Medicine
EDITORIAL FELLOWS:
Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School
Eric J. Epstein, M.D., Albert Einstein College of Medicine
SENIOR ASSOCIATE EDITORS: Donna Goodstein, Amy Faucard
ASSISTANT EDITORS: Cynthia Macapagal Covey, Tracy Shields
MANAGING EDITOR: Susie Wong
PRODUCTION COORDINATOR: Cheryl Brown
DIRECTOR OF CME & EDUCATIONAL PROGRAMS: Catherine H. Bingham
VP FINANCE & OPERATIONS: Yosef Wissner-Levy

Founded in 1959 by
Arthur Kallet and Harold Aaron, M.D.

Copyright and Disclaimer: The Medical Letter is an independent nonprofit organization that provides health care professionals with unbiased drug prescribing recommendations. The editorial process used for its publications relies on a review of published and unpublished literature, with an emphasis on controlled clinical trials, and on the opinions of its consultants. The Medical Letter is supported solely by subscription fees and accepts no advertising, grants or donations. The content of The Medical Letter is controlled by the Editor, who declares no conflict. The members of the Advisory Board are required to disclose any potential conflict of interest.

No part of the material may be reproduced or transmitted by any process in whole or in part without prior permission in writing. The editors do not warrant that all the material in this publication is accurate and complete in every respect. The editors shall not be held responsible for any damage resulting from any error, inaccuracy or omission.

Subscription Services

Mailing Address:
The Medical Letter, Inc.
1000 Main Street
New Rochelle, NY 10801-7537

Customer Service:
Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
Web Site: www.medicalletter.org
E-mail: custserv@medicalletter.org

Permissions:
To reproduce any portion of this issue, please e-mail your request to: permissions@medicalletter.org

Subscriptions (US):
1 year - \$89; 2 years - \$151;
3 years - \$214. \$44.50 per year for students, interns, residents and fellows in the US and Canada.
CME: \$44 for 26 credits.

E-mail site license inquiries to:
info@medicalletter.org or call 800-211-2769 x315.
Special fees for bulk subscriptions. Special classroom rates are available. Back issues are \$12 each. Major credit cards accepted.

Copyright 2006. ISSN 1523-2859