

The Medical Letter®

On Drugs and Therapeutics

Published by The Medical Letter, Inc. • 145 Huguenot Street, New Rochelle, NY 10801 • A Nonprofit Publication

IN THIS ISSUE (starts on next page)

In Brief: Pancreatic Enzyme Products p 11

Important Copyright Message

The Medical Letter® publications are protected by US and international copyright laws. Forwarding, copying or any distribution of this material is prohibited.

Sharing a password with a non-subscriber or otherwise making the contents of this site available to third parties is strictly prohibited.

By accessing and reading the attached content I agree to comply with US and international copyright laws and these terms and conditions of The Medical Letter, Inc.

**For further information click: [Subscriptions](#), [Site Licenses](#), [Reprints](#)
or call customer service at: 800-211-2769**

FORWARDING OR COPYING IS A VIOLATION OF US AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter®

On Drugs and Therapeutics

Published by The Medical Letter, Inc. • 145 Huguenot Street, New Rochelle, NY 10801 • A Nonprofit Publication

Volume 53 (Issue 1357)
February 7, 2011

www.medicalletter.org

IN BRIEF

Pancreatic Enzyme Products

Pancreatic enzyme products (PEPs) have been used for decades to improve digestion in patients with insufficient pancreatic enzyme production, such as those with cystic fibrosis. All porcine-derived PEPs contain a mixture of amylases, lipases and proteases. Since use of PEPs preceded the Federal Food, Drug and Cosmetic Act of 1938, they have been marketed without formal FDA approval,¹ and major differences have been reported between the actual enzyme content in the product and the amount indicated on the label.² In 1991, the FDA announced that all manufacturers of PEPs would be required to submit a new drug application (NDA) for their products to remain on the market; the approval deadline for submitted NDAs was April 28, 2010. As of the deadline, only 3 PEP products had been approved by the FDA and are available commercially. Manufacturers of unapproved PEPs are no longer allowed to distribute their products. Patients taking an unapproved PEP will be required to switch to an FDA-approved product.

Table 1. FDA-Approved PEPs

Product	Cost ¹
Creon (Solvay)	\$92.90
Pancreaze (Ortho-McNeil)	87.59 ²
Zenpep (Eurand)	78.89

1. Cost of 100 capsules of lowest available dosage form, according to *Red Book* 2010.
2. Cost according to a local retail chain pharmacy.

1. FDA. Exocrine pancreatic insufficiency drug products-submitting NDAs. April 2006. Available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071651.pdf>. Accessed January 31, 2011.
2. M Kraisinger et al. Clinical pharmacology of pancreatic enzymes in patients with cystic fibrosis and in vitro performance of microencapsulated formulations. *J Clin Pharmacol* 1994; 34:158.

The Medical Letter®

On Drugs and Therapeutics

EDITOR IN CHIEF: Mark Abramowicz, M.D.
EXECUTIVE EDITOR: Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School
EDITOR: Jean-Marie Pflomm, Pharm.D.
ASSISTANT EDITORS, DRUG INFORMATION: Susan M. Daron, Pharm.D., Blaine M. Houst, Pharm.D., Corinne E. Zanoone, Pharm.D.
CONSULTING EDITOR: Brinda M. Shah, Pharm.D.
CONTRIBUTING EDITORS:
Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons
Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School
Eric J. Epstein, M.D., Albert Einstein College of Medicine
Jules Hirsch, M.D., Rockefeller University
David N. Juurlink, BPhM, M.D., Ph.D., Sunnybrook Health Sciences Centre
Richard B. Kim, M.D., University of Western Ontario
Hans Meinertz, M.D., University Hospital, Copenhagen
Sandip K. Mukherjee, M.D., F.A.C.C., Yale School of Medicine
Dan M. Roden, M.D., Vanderbilt University School of Medicine
F. Estelle R. Simons, M.D., University of Manitoba
Jordan W. Smoller, M.D., Sc.D., Harvard Medical School
Neal H. Steigbigel, M.D., New York University School of Medicine
Arthur M. F. Yee, M.D., Ph.D., F.A.C.R., Weil Medical College of Cornell University
SENIOR ASSOCIATE EDITORS: Donna Goodstein, Amy Faucard
ASSOCIATE EDITOR: Cynthia Macapagal Covey
EDITORIAL FELLOW: Esperance A.K. Schaefer, M.D., M.P.H., Massachusetts General Hospital, Harvard Medical School
MANAGING EDITOR: Susie Wong
ASSISTANT MANAGING EDITOR: Liz Donohue
PRODUCTION COORDINATOR: Cheryl Brown
EXECUTIVE DIRECTOR OF SALES: Gene Carbona
FULFILLMENT & SYSTEMS MANAGER: Cristine Romatowski
DIRECTOR OF MARKETING COMMUNICATIONS: Joanne F. Valentino
VICE PRESIDENT AND PUBLISHER: 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.

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.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537

Subscriptions (US):
1 year - \$98; 2 years - \$189;
3 years - \$279. \$49.00 per year for students, interns, residents and fellows in the US and Canada.

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

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.

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

Copyright 2011. ISSN 1523-2859