

The Medical Letter[®]

on Drugs and Therapeutics

Volume 59

October 9, 2017

ISSUE No.

1531

IN THIS ISSUE

In Brief: Pancreatic Enzyme Replacement Products p 170

Important Copyright Message

FORWARDING OR COPYING IS A VIOLATION OF U.S. AND INTERNATIONAL COPYRIGHT LAWS

The Medical Letter, Inc. publications are protected by U.S. 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 U.S. 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

The Medical Letter[®]

on Drugs and Therapeutics

Volume 59

October 9, 2017

IN BRIEF

Pancreatic Enzyme Replacement Products

Pancreatic enzyme replacement products have been used for years to improve digestion in patients with exocrine pancreatic insufficiency (EPI). These products were initially marketed before formal FDA approval was required; in 1991, however, the FDA told all manufacturers of pancreatic enzyme replacement products that they would have to submit a new drug application by April 2010 in order to keep their products on the market.

EPI is a chronic disorder characterized by a deficiency of exocrine pancreatic enzymes, which results in malabsorption, steatorrhea, and weight loss. Irreversible EPI is commonly caused by chronic pancreatitis in adults and

by cystic fibrosis in children. The standard treatment for EPI is pancreatic enzyme replacement therapy. Treatment with pancreatic enzyme replacement products has reduced fat malabsorption and steatorrhea.¹

All pancreatic enzyme replacement products in the US contain a mixture of porcine-derived amylases, lipases, and proteases. All of the products except *Viokace* are available in delayed-release capsules containing enteric-coated beads, spheres, microspheres, or microtablets to protect lipase from denaturation by gastric acid. *Viokace* immediate-release tablets should be taken with a proton pump inhibitor to improve release of pancreatic enzymes in the duodenum.² Because the rate and extent of dissolution of these products vary, they are not considered interchangeable.

Pancreatic enzyme replacement products are generally well tolerated. Common adverse effects include headache, dizziness, abdominal pain, and flatulence.

The dosage for children and adults ≥ 4 years old with EPI is based on body weight, degree of steatorrhea present, and dietary fat content. The recommended dosage of all pancreatic enzyme replacement products is 500 lipase units/kg/meal (maximum 2500 units/kg/meal or $\leq 10,000$ units/kg/day) or < 4000 units/g of fat ingested/day. Older adults may need a lower dose because they ingest less fat per kilogram of body weight. Half the dose for a meal should be taken with each snack. The dosage for children < 4 years old is based on Cystic Fibrosis Foundation Consensus Conference Guidelines.³

Table 1. FDA-Approved Pancreatic Enzyme Replacement Products for EPI¹

Drug	Available Strengths	Cost ²
Immediate-release –		
<i>Viokace</i> (Allergan) ³⁻⁵	10,440 or 20,880 units of lipase ⁶	\$8.80
Delayed-release –		
<i>Creon</i> (Abbvie)	3000, 6000, 12,000, 24,000, or 36,000 USP units of lipase ^{6,7}	8.20
<i>Pancreaze</i> (Janssen)	2600, 4200, 10,500, 16,800, or 21,000 units of lipase ^{6,7}	8.80
<i>Pertzye</i> (Digestive Care)	4000, 8000, 16,000, or 24,000 units of lipase ^{6,7}	8.40
<i>Zenpep</i> (Allergan)	3000, 5000, 10,000, 15,000, 20,000, 25,000, or 40,000 units of lipase ^{6,7}	9.60

1. Pancrelipase products are not interchangeable. All of these products contain a combination of porcine-derived lipases, proteases, and amylases.
2. Approximate WAC for one dose (as close as possible to 35,000 USP units of lipase using available formulations) for a 70-kg patient. WAC = wholesaler acquisition cost, or manufacturer's published price to wholesalers; WAC represents published catalogue or list prices and may not represent an actual transactional price. Source: AnalySource® Monthly. September 5, 2017. Reprinted with permission by First Databank, Inc. All rights reserved. ©2017. www.fdbhealth.com/policies/drug-pricing-policy.
3. *Viokace* is only approved for use in adults.
4. Should be used in combination with a proton pump inhibitor to maximize absorption in the duodenum.
5. FDA- approved only for treatment of adults with EPI due to chronic pancreatitis or pancreatectomy.
6. Should not be crushed or chewed.
7. Capsules can be opened and contents sprinkled on soft acidic food (pH ≤ 4.5) such as applesauce.

1. A Fieker et al. Enzyme replacement therapy for pancreatic insufficiency: present and future. *Clin Exp Gastroenterol* 2011; 4:55.
2. MR Struyvenberg et al. Practical guide to exocrine pancreatic insufficiency – breaking the myths. *BMC Med* 2017; 15:29.
3. PM Farrell et al. Diagnosis of cystic fibrosis: consensus guidelines from the Cystic Fibrosis Foundation. Available at: [www.jpeds.com/article/S0022-3476\(16\)31048-4/pdf](http://www.jpeds.com/article/S0022-3476(16)31048-4/pdf). Accessed September 28, 2017.

Follow us on Twitter  Like us on Facebook 

PRESIDENT: Mark Abramowicz, M.D.; **VICE PRESIDENT AND EXECUTIVE EDITOR:** Gianna Zuccotti, M.D., M.P.H., F.A.C.P., Harvard Medical School; **EDITOR IN CHIEF:** Jean-Marie Pflomm, Pharm.D.; **ASSOCIATE EDITORS:** Susan M. Daron, Pharm.D., Amy Faucard, MLS, Corinne Z. Morrison, Pharm.D., Michael P. Viscusi, Pharm.D.; **CONSULTING EDITORS:** Brinda M. Shah, Pharm.D., F. Peter Swanson, M.D.

CONTRIBUTING EDITORS: Carl W. Bazil, M.D., Ph.D., Columbia University College of Physicians and Surgeons; **Ericka L. Crouse, Pharm.D., B.C.P.P., C.G.P., F.A.S.H.P., F.A.S.C.P.,** Virginia Commonwealth University Health; **Vanessa K. Dalton, M.D., M.P.H.,** University of Michigan Medical School; **Eric J. Epstein, M.D.,** Albert Einstein College of Medicine; **David N. Juurlink, BPhM, M.D., Ph.D.,** Sunnybrook Health Sciences Centre; **Richard B. Kim, M.D.,** University of Western Ontario; **Franco M. Muggia, M.D.,** New York University Medical Center; **Sandip K. Mukherjee, M.D., F.A.C.C.,** Yale School of Medicine; **Dan M. Roden, M.D.,** Vanderbilt University School of Medicine; **Esperance A.K. Schaefer, M.D., M.P.H.,** Harvard Medical School; **F. Estelle R. Simons, M.D.,** University of Manitoba; **Neal H. Steigbigel, M.D.,** New York University School of Medicine; **Arthur M. F. Yee, M.D., Ph.D., F.A.C.R.,** Weill Medical College of Cornell University

MANAGING EDITOR: Susie Wong; **ASSISTANT MANAGING EDITOR:** Liz Donohue

FULFILLMENT AND SYSTEMS MANAGER: Cristine Romatowski; **SITE LICENSE SALES:** Elaine Reaney-Tomaselli; **EXECUTIVE DIRECTOR OF MARKETING AND 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, Inc. is an independent nonprofit organization that provides healthcare 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, Inc. does not sell advertising or receive any commercial support. 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

Address:
The Medical Letter, Inc.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537
www.medicalletter.org

Customer Service:
Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
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 - \$159; 2 years - \$298;
3 years - \$398. \$65 per year
for students, interns, residents, and
fellows in the US and Canada.
Reprints - \$25/article, \$35/issue

Site License Inquiries:
E-mail: SubQuote@medicalletter.org
Call: 800-211-2769
Special rates available for bulk
subscriptions.

Get Connected:  

Copyright 2017. ISSN 1523-2859

The
Medical
Letter