

The Medical Letter[®]

on Drugs and Therapeutics

Volume 58

July 4, 2016

ISSUE No.
1498

IN THIS ISSUE

In Brief: Uridine Triacetate (*Vistogard*) for Fluorouracil Overdose..... p 90

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 58 (Issue 1498)

July 4, 2016

IN BRIEF

Uridine Triacetate (*Vistogard*) for Fluorouracil Overdose

The FDA has approved the pyrimidine analog uridine triacetate (*Vistogard* – Wellstat Therapeutics) for emergency treatment of a fluorouracil (5-FU) or capecitabine (*Xeloda*, and generics) overdose or severe toxicity that occurs within 96 hours following administration of one of these drugs. Fluorouracil is a cytotoxic antimetabolite used to treat breast, colorectal, and other cancers; capecitabine is an oral prodrug of fluorouracil.

Uridine triacetate, a prodrug, is deacetylated to uridine after oral administration. Excess circulating uridine is converted into uridine triphosphate, which inhibits the cytotoxic activity of 5-fluorouridine triphosphate, a fluorouracil metabolite, by competing with it for incorporation into RNA.

FDA approval was based on two unpublished open-label studies (summarized in the package insert) in a total of 135 adults and children with overdoses of fluorouracil or capecitabine (n=117) or severe or life-threatening toxicities within 96 hours after their administration (n=18). The overall survival rate at 30 days was 96%.

In retrospective case reports that included 25 patients who received only supportive care after a fluorouracil overdose, the survival rate was 16%.

Vistogard is supplied as orange-flavored oral granules in single-dose packets containing 10 grams of uridine triacetate. The granules should be mixed with 3-4 ounces of soft food and taken every 6 hours for 20 doses. The recommended dose is 10 grams for adults and 6.2 grams/m² (10 grams maximum) for children. Mild to moderate nausea, vomiting, and diarrhea have been reported. The cost for one course of treatment is \$75,000.¹ ■

1. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. June 5, 2016. Reprinted with permission by First Databank, Inc. All rights reserved. ©2016. www.fdbhealth.com/policies/drug-pricing-policy.

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; Vanessa K. Dalton, M.D., M.P.H., University of Michigan Medical School; Eric J. Epstein, M.D., Albert Einstein College of Medicine; Jane P. Gagliardi, M.D., M.H.S., F.A.C.P., Duke University School 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; **EDITORIAL ASSISTANT:** Cheryl Brown

EXECUTIVE DIRECTOR OF SALES: Gene Carbona; **FULFILLMENT AND SYSTEMS MANAGER:** Cristine Romatowski; **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. 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

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 - \$129; 2 years - \$232;
3 years - \$345. \$65 per year
for students, interns, residents, and
fellows in the US and Canada.
Reprints - \$12 each.

Site License Inquiries:
E-mail: info@medicalletter.org
Call: 800-211-2769 ext. 315
Special rates available for bulk
subscriptions.

