A CME/CE CERTIFIED SUPPLEMENT TO

Seminars in Cutaneous Medicine and Surgery

Onychomycosis: Diagnosis, Treatment, and Prevention Strategies

GUEST EDITORS

Linda F. Stein Gold, MD Theodore Rosen, MD

Introduction \$47

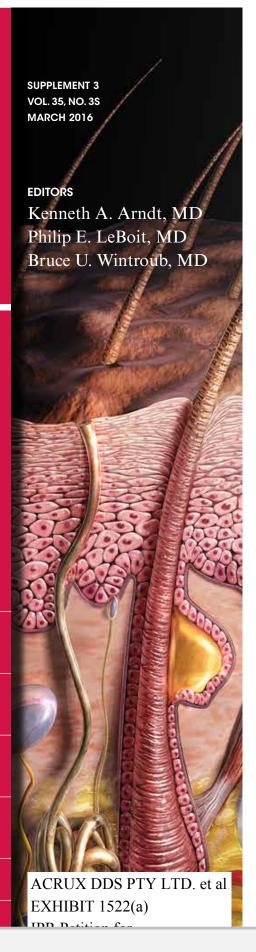
Understanding Onychomycosis:
Resolving Diagnostic Dilemmas S48

Antifungal Drugs for Onychomycosis:
Efficacy, Safety, and Mechanisms of Action S51

Concepts in Onychomycosis Treatment and Recurrence Prevention: An Update S56

Using Topical Antifungal Medications:
Instructions for Patients S60

Post-Test and Evaluation Form S61





A CME/CE CERTIFIED SUPPLEMENT TO

Seminars in Cutaneous Medicine and Surgery

Onychomycosis: Diagnosis, Treatment, and Prevention Strategies

GUEST EDITORS
Linda F. Stein Gold, MD
Theodore Rosen, MD

Introduction \$47

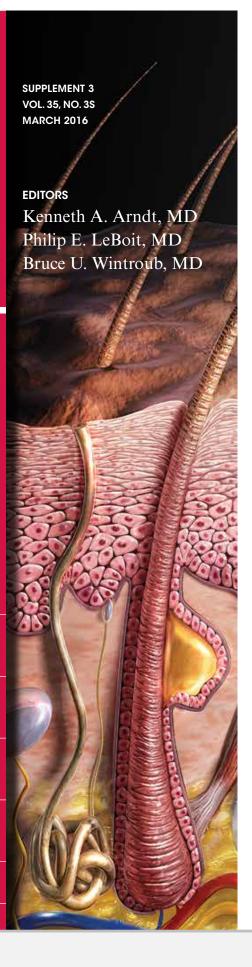
Understanding Onychomycosis:
Resolving Diagnostic Dilemmas S48

Antifungal Drugs for Onychomycosis:
Efficacy, Safety, and Mechanisms of Action S51

Concepts in Onychomycosis Treatment and Recurrence Prevention: An Update S56

Using Topical Antifungal Medications:
Instructions for Patients S60

Post-Test and Evaluation Form S61





Onychomycosis: Diagnosis, Treatment, and Prevention Strategies

Original Release Date: March 2016 Most Recent Review Date: March 2016 Expiration Date: February 28, 2018

Estimated Time to Complete Activity: 2.5 hours

Participants should read the activity information, review the activity in its entirety, and complete the online post-test and evaluation. Upon completing this activity as designed and achieving a passing score on the post-test, you will be directed to a Web page that will allow you to receive your certificate of credit via e-mail or you may print it out at that time. The online post-test and evaluation can be accessed at http://tinyurl.com/onychosuppl16.

Inquiries about CME accreditation may be directed to the University of Louisville CME & PD at cmepd@louisville.edu or (502)852-5329.

Accreditation Statements

Physicians: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of The University of Louisville and Global Academy for Medical Education, LLC. The University of Louisville is accredited by the ACCME to provide continuing medical education for physicians.

The University of Louisville Office of Continuing Medical Education & Professional Development designates this enduring material for a maximum of 2.5 AMA PRA Category 1 CreditsTM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses: This program has been approved by the Kentucky Board of Nursing for 3.0 contact hours through the University of Louisville Hospital, provider number 4-0068-7-16-895. The Kentucky Board of Nursing approval of an individual nursing education provider does not constitute endorsement of program content. Participants must complete the entire session, provide their license number, and complete the evaluation to receive contact hours.

Target Audience

This journal supplement is intended for dermatologists, family practitioners, internists, nurse practitioners, physician assistants, and other clinicians who treat patients with onychomycosis.

Educational Needs

For many years, the treatment of onychomycosis was frustrating for clinicians and patients alike, and the perceived futility of addressing fungal nail infections meant that many patients failed to seek treatment, and many others with suspected infections were neither definitively diagnosed nor treated. With the introduction of oral terbinafine in 1996 and the approval of the first topical agent in 1999, more effective control—if not cure—became possible, and clinicians showed increased interest in diagnosing and treating the condition. The introduction of two new topical agents in 2014 broadened the therapeutic options.

The optimum results with these agents requires the correct diagnosis, which cannot be made reliably on visual inspection alone. To use antifungals most effectively, clinicians must test to confirm the presence of infecting organisms and, in appropriate cases, identify the species involved so that the most appropriate antifungal can be prescribed. Patient selection also is important: for example, the potential for drug-drug interactions with systemic antifungals must be considered, the presence of certain comorbid conditions may affect the choice of antifungal employed, and the patient's ability to adhere to the long treatment regimens required must be addressed.

Clinicians must remain up-to-date on these issues, and must be able to effectively and safely use the available antifungal, evaluate the emerging data on medications and devices now being investigated, and educate patients to improve adherence.

Learning Objectives

After reading and studying this journal supplement, participants will be better able to:

- Establish or improve practice protocols for identifying patients with onychomycosis, particularly in special populations (eg, the elderly, pediatric patients, immunocompromised patients, patients with psoriasis, and those with diabetes mellitus).
- · Discuss techniques, including obtaining good culture specimens, that

permit more accurate diagnosis of the infecting organisms and the most appropriate choice of therapy.

- Explain the drug classes and mechanisms of action for the currently available therapeutic options, including differences in formulation and associated efficacy.
- More effectively use currently available oral and topical medications to treat various patient populations.
- Review and, if necessary, improve patient education materials designed to enhance patient adherence with the treatment regimen and to change habits that increase the chances of good long-term management of onvchomycosis.
- Determine and help each patient recognize the realistic expectations for improvement in his or her individual case.
- Evaluate the results of clinical studies on new and emerging and available treatments for onychomycosis based on an understanding of possible differences in testing protocols (eg, inclusion or exclusion of patients with psoriasis or diabetes mellitus).

Disclosure Declarations

As a provider accredited by the ACCME, the Office of CME & PD, School of Medicine, University of Louisville must ensure balance, independence, objectivity, and scientific rigor in all its sponsored educational activities. All planners, faculty, reviewers, and other persons that affected the content of this CME activity were required to submit a financial disclosure form from which relevant conflicts of interest were determined. The persons below disclosed the following:

Linda F. Stein Gold, MD, Consultant: Anacor Pharmaceuticals Inc., Eli Lilly and Company, Galderma Laboratories, L.P., LEO Pharma Inc., Novartis Pharmaceuticals Corporation, Pfizer Inc., Sandoz, Taro Pharmaceutical Industries Ltd., and Valeant Pharmaceuticals North America LLC. Speaker: Galderma, LEO, Novartis, and Valeant. Grant Research/Support: Anacor, Galderma, GlaxoSmithKline, LEO, Novartis, Pfizer Inc., Sandoz, Taro, and Valeant.

Theodore Rosen, MD, Consultant: Anacor Pharmaceuticals and Valeant Pharmaceuticals North America LLC.

CME Reviewer: Cindy England Owen, MD, Assistant Professor, Division of Dermatology, University of Louisville School of Medicine, has no relevant financial relationships to disclose.

The CME & PD Staff and Advisory Board have nothing to disclose with the exception of Douglas Coldwell, MD, Speaker: Sirtex, Inc.; Consultant: DFine, Inc.

Global Academy for Medical Education Staff: Sylvia H. Reitman, MBA, DipEd; Shirley V. Jones, MBA; Jenny Campano; and Joanne Still have no relevant financial relationships to disclose.

Off-Label/Investigational Use Disclosure

This CME/CE activity discusses the off-label use of fluconazole for the treatment of onychomycosis. Also discussed are off-label, alternative dosing schedules for itraconazole, as well as the use in pediatric patients of medications approved for the treatment of onychomycosis in adults; currently, no medication is approved for the treatment of onychomycosis in pediatric patients.

This continuing education supplement was developed from a satellite symposium held at Skin Disease Education Foundation (SDEF)'s 16th Annual Las Vegas Dermatology Seminar, which took place Friday, November 6, 2015, in Las Vegas, Nevada. The Guest Editors acknowledge the editorial assistance of Global Academy for Medical Education and Joanne Still, medical writer, in the development of this supplement. The manuscript was reviewed and approved by the Guest Editors as well as the Editors of Seminars in Cutaneous Medicine and Surgery. The ideas and opinions expressed in this supplement are those of the Guest Editors and do not necessarily reflect the views of the supporters, Global Academy for Medical Education, the University of Louisville, or the Publisher.



Seminars in Cutaneous Medicine and Surgery

EDITORS



Kenneth A. Arndt, MD
Clinical Professor of Dermatology,
Emeritus
Harvard Medical School
Adjunct Professor of Surgery
Dartmouth Medical School
Hanover, New Hampshire
Adjunct Professor of Dermatology
Brown Medical School
Providence, Rhode Island



Philip E. LeBoit, MD
Professor of
Clinical Dermatology
University of California,
San Francisco
San Francisco, California



Bruce U. Wintroub, MD Associate Dean Professor and Chair of Dermatology School of Medicine University of California,

STATEMENT OF PURPOSE

Seminars in Cutaneous Medicine and Surgery presents well-rounded and authoritative discussions of important clinical areas, especially those undergoing rapid change in the specialty. Each issue, under the direction of the Editors and Guest Editors selected because of their expertise in the subject area, includes the most current information on the diagnosis and management of specific disorders of the skin, as well as the application of the latest scientific findings to patient care.

Seminars in Cutaneous Medicine and Surgery (ISSN 1085-5629) is published quarterly by Frontline Medical Communications Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609. Months of issue are March, June, September, and December. Periodicals postage paid at Parsippany, NJ, and additional mailing offices.

POSTMASTER: Send address changes to Seminars in Cutaneous Medicine and Surgery, Subscription Services, 151 Fairchild Ave., Suite 2, Plainview, NY 11803-1709.

RECIPIENT: To change your address, contact Subscription Services at 1-800-480-4851

Editorial correspondence should be addressed to Kenneth A. Arndt, MD, SkinCare Physicians of Chestnut Hill, 1244 Boylston St, Suite 302, Chestnut Hill, MA 02467. Correspondence regarding subscriptions or change of address should be directed to the Publisher, Subscription Services, 151 Fairchild Ave., Suite 2, Plainview, NY 11803-1709, 1-800-480-4851.

Yearly subscription rate: \$121.00 per year.

Prices are subject to change without notice. Current prices are in effect for back volumes and back issues. Single issues, both current and back, exist in limited quantities and are offered for sale subject to availability. Back issues sold in conjunction with a subscription are on a prorated basis.

Copyright © 2016 by Frontline Medical Communications Inc. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopy, recording, or any information storage and retrieval system, without written permission from the Publisher. Printed in the United States of America.

Advertising representative: Sally Cioci, 7 Century Drive, Suite 302, Parsippany, NJ 07054-4609. Phone: 973-206-3434; Fax: 973-206-9378; email: scioci@frontlinemedcom.com

Publication of an advertisement in *Seminars in Cutaneous Medicine and Surgery* does not imply endorsement of its claims by the Editor(s) or Publisher of the journal.

The ideas and opinions expressed in Seminars in Cutaneous Medicine and Surgery do not necessarily reflect those of the Editors or Publisher. Publication of an advertisement or other product mention in Seminars in Cutaneous Medicine and Surgery should not be construed as an endorsement of the product or the manufacturer's claims. Readers are encouraged to contact the manufacturer with any questions about the features or limitations of the products mentioned. The Publisher does not assume any responsibility for any injury and/or damage to persons or property arising out of or related to any use of the material contained in this periodical. The reader is advised to check the appropriate medical literature and the product information currently provided by the manufacturer of each drug to be administered to verify the dosage, the method and duration of administration, or contraindications. It is the responsibility of the treating physician or other health care professional, relying on independent experience and knowledge of the patient, to determine drug dosages and the best treatment for the patient.

Seminars in Cutaneous Medicine and Surgery is indexed in Index



TABLE OF CONTENTS

Onychomycosis: Diagnosis, Treatment, and Prevention Strategies

\$47 Introduction
Linda F. Stein Gold, MD

S56 Concepts in Onychomycosis
Treatment and Recurrence
Prevention: An Update
Theodore Rosen, MD

S48 Understanding Onychomycosis: Resolving Diagnostic Dilemmas Linda F. Stein Gold, MD

\$60 Using Topical Antifungal Medications: Instructions for Patients Theodore Rosen, MD

\$51 Antifungal Drugs for Onychomycosis: Efficacy, Safety, and Mechanisms of Action

\$61 Post-Test and Evaluation Form

Theodore Rosen, MD, and Linda F. Stein Gold, MD

GUEST EDITORS



Linda F. Stein Gold, MD
Director of Dermatology Research
Henry Ford Health System
Detroit, Michigan



Theodore Rosen, MD, Professor of Dermatology Baylor College of Medicine Houston, TX

DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

