

PREFACE

The newly revised and updated nineteenth edition of the *Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care* is a comprehensive and authoritative textbook on self-care and nonprescription medications. The major goals for this edition were to

- enhance the content in all chapters from the previous edition with up-to-date information beneficial to all health care providers and students
- update the universal objectives to complement the content in the chapters focused on medical disorders
- add a chapter that focused on pre- and probiotics, because their popularity and science describing their use have grown considerably since the last edition

This edition remains true to the spirit of previous editions, namely to assist health care providers and students in developing knowledge and problem-solving skills needed to

- assess a patient's health status, medical problems, and current practice of self-treatment, including nonprescription and prescription medications, dietary supplements, and other self-care measures
- determine whether self-care and/or self-testing and monitoring are necessary and/or appropriate
- if appropriate, recommend safe and effective self-care measures, taking into account the patient's treatment preferences

Written and reviewed by experts in practice and academia, this edition of the *Handbook* continues to serve as an authoritative source for students and health care providers who guide and care for individuals undertaking self-treatment.

Major Changes in the New Edition

- A rewrite of Chapter 1, "Self-Care and Nonprescription Pharmacotherapy," with a focus on some of the more contemporary issues affecting self-care, the self-care consumer, nonprescription products, the role of health care reform, changes in pharmacy practice as they relate to self-care, and health care in general.
- A rewrite of Chapter 2, "Patient Assessment and Consultation," so that the content is more applicable and practical to the self-care/nonprescription product environment. Case

studies that illustrate the use of a more abbreviated problem-solving model were added.

- Addition of a chapter that covers pre- and probiotics.
- Removal of the pregnancy risk categories for all drugs and natural products and, subsequently, the removal of the two appendices that focused on pregnancy risk information.
- Use of standardized, consistent terminology for issues that are discussed in multiple chapters.
- Availability of an online version of the book that will reside on APhA's digital platform PharmacyLibrary (www.pharmacylibrary.com) and allow updating and/or revision of chapters, as needed.
- Incorporation of vaccine information into certain chapters where the content is synergistic.
- For the print and online versions of the book, provision of two new comprehensive patient cases per chapter that are based on the revised eighteenth edition case format.
- For only the online version of the book, provision of additional cases based on the abbreviated case format that was introduced in the seventeenth edition.
- Removal of Chapter 45, "Self-care Components of Selected Chronic Diseases," because a majority of the content was not applicable to self-care.

Removal of Pregnancy Risk Categories

Removal of pregnancy risk categories was based on regulatory action of the Food and Drug Administration (FDA). In 2015 FDA implemented the Pregnancy and Lactation Labeling Rule (PLLR), which replaces the former pregnancy risk letter categories (A, B, C, D, X) for prescription drugs with more descriptive content in the following fields:

- Pregnancy: now includes labor and delivery
- Lactation
- Females and males of reproductive potential

Although this new categorization provides clinicians with more detail for decision making, clinicians still need to apply this information on a case-by-case basis. The PLLR will be implemented in phases, with the final phase to be completed by June 29, 2018. However, this rule is not applicable to self-care and nonprescription products. Readers can find detailed information about the rule at the following websites:

- <https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/labeling/ucm093307.htm>

- <https://www.federalregister.gov/documents/2014/12/04/2014-23241/content-and-format-of-labeling-for-human-prescription-drug-and-biological-products-requirements-for>

Previous editions of the *Handbook* have included pregnancy risk letter designations, where available, and oftentimes this information was based on the designation for the prescription version of the medication. With the changes that have taken place and the lack of support for letter designations to identify pregnancy risk, the editors decided to remove any reference to a pregnancy risk category within the chapters and to remove both appendices. Where this information appeared previously, we now include general language that supports the reader in determining, based on available literature, what is best for their particular patient in each situation. The following is the standard language in all chapters that mention medication or product use in pregnancy:

- See the Preface for a detailed explanation of the pregnancy data.
- Use in pregnancy should be limited to clinical situations in which the potential benefit justifies potential risk to the fetus.

Where a pregnancy issue exists for a nonprescription product, the Drug Facts Label states that the consumer should ask a health care professional before using the product if she is pregnant or breastfeeding. FDA is aware of the limitations of the Drug Facts Label for communicating complex issues such as pregnancy labeling. They attempt to ensure nonprescription labeling is as consistent as possible with the prescription drug labels when a drug is available in both forms. However, the challenge with nonprescription products is to provide information that consumers can understand but is detailed enough to address any concerns. FDA is aware of the inconsistencies this situation has created and, at the time of this writing, was discussing options to enhance information for use of these products during pregnancy.

Use of Consistent Terminology Among Chapters

Another major focus area of the nineteenth edition was ensuring standardized, consistent terminology for issues that are discussed in multiple chapters. Two examples that have significant reach in this edition of the *Handbook* are Reye's syndrome and measurement of liquid medication doses. The manner in which each has been addressed is described here.

Reye's Syndrome Definition

The following information is included in Chapter 5, "Headache" and is the standard; all other chapters that discuss this issue cross-reference Chapter 5.

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Measurement of Liquid Medications

The following information on measurement of liquid medications is now included in Chapter 11, "Disorders Related to Colds and Allergy," and is the standard; all other chapters that discuss this issue cross-reference Chapter 11.

To address the issue of inaccurate dosing, FDA released guidelines in May 2011 for liquid nonprescription drug products that include any type of dispensing device (dropper, cup, syringe, spoon). (See the full document at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM188992.pdf>.) Products include liquid analgesics, liquid cough and cold products, and lactase replacement drops. The key points of the guidelines are as follows:

- A dosing device should be included with all oral liquid nonprescription products.
- The device should be calibrated to the dose recommended in the product directions.
- The device should be used only with the product in which it is packaged.
- The markings need to remain visible even when the liquid is in the device.

Objectives of Disorder Chapters

Self-care opportunities exist for many individuals with myriad health disorders. The content presented in this text that focuses on disorders lends itself to the objectives listed below. The editors encourage you to review and utilize these objectives to help you gain the greatest benefit from the information presented in the disorder-related chapters. For each patient complaint

- identify its most likely underlying cause(s)
- identify common signs and symptoms
- determine whether the complaint is amenable to self-care, the patient requires referral, or nothing needs to be done
- identify the FDA-approved monograph active ingredients in a given nonprescription drug category
- determine common side effects for a given category of nonprescription drugs
- determine contraindications to the use of a given category of nonprescription drugs or devices
- distinguish indications and limitations for use of nonprescription drugs or devices in a given category
- explain nondrug measures commonly used in treatment or prevention
- develop an appropriate plan for a given patient who seeks self-care advice
- formulate a list of key counseling points to educate a patient on the appropriate use of nonprescription drugs, nondrug measures, or a device

Highlights of New Features and Revisions

Considerable time and effort have been invested in improving this edition. We are hopeful that the following changes improve the quality and usability of the book, as well as provide increased clarity and convenience.

- Chapter 1, "Self-Care and Nonprescription Pharmacotherapy"
 - New authors, new approach to introducing self-care to the reader
 - Focus on today's health care and self-care consumer
 - Role of health care reform in self-care
 - Role of today's pharmacist and approach to patient care in self-care

- How self-care fits with the traditional *medication therapy management* model
- Value of self-care
- Importance of consumer education
- Author’s vision of the future of self-care
- Chapter 2, “Pharmacists’ Patient Care Process in Self-care”
 - Description of the Pharmacists Patient Care Process (PPCP)
 - Description of how more traditional self-care patient assessment processes, such as QuEST/SCHOLAR, relate to PPCP
 - Addition of new case studies to illustrate application of these assessment processes
 - Overview of patient-centered self-care
 - Discussion of special populations and PPCP in self-care
 - A rewrite of Chapter 2 was completed to make the content even more applicable to and practical for the self-care/nonprescription product environment, and to describe the relationship between PPCP and self-care patient assessment processes. As mentioned in the previous edition, part of our responsibility as educators is to expose our students to multiple options for assessing patients in self-care. Although the traditional approach in the *Handbook* was to focus solely on the very complex process, we realized other approaches, such as those that better fit situations when health care providers have more experience and/or limited time to interact with a patient, are important to discuss. One of these abbreviated processes, QuEST/SCHOLAR-MAC, is again used as the basis for the electronic cases written to enhance the application of content in the disorder-related chapters. These supplemental cases are available on APhA’s digital subscription product PharmacyLibrary at www.pharmacylibrary.com. In addition, two new comprehensive patient cases are included in each chapter.
- Chapter 3, “Exploring Cultural Aspects of Self-care”
 - Additional emphasis on definitions of key terms
 - Updated demographics to illustrate diversity
 - Discussion of how lack of awareness of culture issues and health disparities among health care providers can contribute to disparities
 - Expanded focus on all minorities who may be affected, including the lesbian, gay, bisexual, and transgender community
 - Detailed information on models for communicating with patients across cultures
 - Comprehensive list of resources for developing a more culturally competent healthcare environment
- Chapter 4, “Legal and Regulatory Issues in Self-care Pharmacy Practice”
 - Description of the history of self-care and list of key FDA guidance documents related to nonprescription products
 - Updated list of Rx-to-OTC switches
 - Factors to address regarding the safe use of nonprescription products
 - Discussion of a third class of drugs and what is happening in the United States versus other countries
 - Cosmetics that could also be considered drugs
 - Point-of-care diagnostic devices and the Clinical Laboratory Improvement Amendments program
 - Liability and nonprescription products
- Chapter 5, “Headache”
 - Updated medication dosing table
 - Detailed information regarding FDA boxed warnings for acetaminophen and hepatotoxicity and severe skin reactions
- New information about gastrointestinal and cardiovascular risks with nonsteroidal anti-inflammatory drugs
- Chapter 7, “Musculoskeletal Injuries and Disorders”
 - Addition of information regarding the use of topical anesthetics
- Chapter 9, “Disorders Related to Menstruation”
 - Expanded discussion of premenstrual disorders (premenstrual syndrome, premenstrual dysphoric disorder)
- Chapter 10, “Prevention of Pregnancy and Sexually Transmitted Infections”
 - Expanded discussion of human papillomavirus
- Chapter 11, “Disorders Related to Cold and Allergy”
 - Enhanced content in the table Clinically Important Drug–Drug Interactions With Cold and Allergy Products that also includes a management/prevention section
 - Addition of intranasal corticosteroids to the allergic rhinitis section
 - Addition of a new table, Nonprescription Intranasal Corticosteroid Products and Dosage Guidelines
- Chapter 12, “Cough”
 - Addition of a new table, Clinically Important Drug–Drug Interactions With Nonprescription Antitussive Agents
 - Updates regarding the use of codeine in children
- Chapter 13, “Heartburn and Dyspepsia”
 - Addition of a new table, Clinically Important Drug–Drug Interactions With Nonprescription Heartburn and Dyspepsia Agents
- Chapter 16, “Diarrhea”
 - Addition of a new table, Clinically Important Drug–Drug Interactions With Nonprescription Antidiarrheal Agents
- Chapter 19, “Nausea and Vomiting”
 - Addition of a new table, Selected Nonprescription Antiemetic Products and Common Drug Interactions
- Chapter 20, “Prebiotics and Probiotics” (new chapter)
 - Definitions
 - Sources
 - Uses, doses, evidence, and potential risks
- Chapter 23, “Essential and Conditionally Essential Nutrients”
 - Updated information related to calcium and vitamin D
 - Addition of figures for iron, folic acid, and vitamin B₁₂
 - Most nutrients did not have major changes
- Chapter 24, “Functional and Meal Replacement Foods”
 - Removal of “Probiotics” section to new Chapter 20, “Prebiotics and Probiotics”
- Chapter 25, “Sports Nutrition and Performance-Enhancing Nutrients”
 - Discussion of new products and their role, if any, in recreational/nonprofessional sports
 - Addition of two new reviewers who specialize in sports nutrition, including one who works with a national sports team
- Chapter 26, “Infant Nutrition and Special Nutritional Needs of Children”
 - Updated information on available products
 - Updated information on which growth charts to use. Note: Specialized growth charts are no longer recommended by the AAP guidelines for children with Down syndrome.
- Chapter 27, “Overweight and Obesity”
 - Inclusion of most recent prevalence data
 - Introduction of the concept of the gut microbiome potentially contributing to obesity
 - Discussion of carbohydrate-restriction versus fat-restriction for weight loss

- Chapter 29, “Otic Disorders”
 - Creation of an enhanced version of the table Selected Products for Use With Gas-Permeable Lenses
- Chapter 31, “Prevention of Hygiene-Related Oral Disorders”
 - Addition of description of ADA Seal of Acceptance
- Chapter 32, “Oral Pain and Discomfort”
 - Information about risks associated with homeopathic teething products
 - Addition of content related to treatment in special populations
- Chapter 33, “Otic Disorders”
 - Addition of content related to treatment in special populations
- Chapter 35, “Contact Dermatitis”
 - Addition of a new table, Usage Guidelines for Products That Remove Urushiol
 - Addition of a new table, Usage Guidelines for Burow’s Solution
- Chapter 36, “Diaper Dermatitis and Prickly Heat”
 - Expansion of the table Selected Nonprescription Products for Diaper Dermatitis
- Chapter 37, “Insect Stings and Bites and Pediculosis”
 - Updated information regarding effectiveness of nonprescription pediculicides
- Chapter 38, “Acne”
 - Addition of information on a new antiacne product, adapalene gel 0.1% (Differin Gel)
- Chapter 39, “Prevention of Sun-Induced Skin Disorders”
 - Updated information on use of sunscreens in infants
- Chapter 40, “Skin Hyperpigmentation and Photoaging”
 - Inclusion of a table describing Fitzpatrick skin types as they relate to skin pigmentation
- Chapter 41, “Minor Burns, Sunburn, and Wounds”
 - Inclusion of an update on the role of antibacterial soaps in prevention of infection
- Chapter 43, “Warts”
 - Addition of information on treatment of warts in special populations
- Chapter 44, “Minor Foot Disorders”
 - Discussion of tired aching feet combined with exercise-induced foot injuries
- Chapter 45, “Hair Loss”
 - Addition of information on the management of hair loss in special populations
- Chapter 46, “Insomnia, Drowsiness, and Fatigue”
 - Addition of new drug interaction tables, Clinically Significant Drug Interactions With Diphenhydramine and Clinically Significant Drug Interactions With Caffeine
- Chapter 47, “Tobacco Cessation”
 - Provision of additional information about e-cigarettes
- Chapter 48, “Home Testing and Monitoring Devices”
 - Addition of a case focused on home testing for hepatitis C
- Chapter 51, “Natural Products”
 - Updated list of natural products
 - Revisions focused on enhancing content regarding key uses and issues for each product
 - Addition of a new section, “Weight-Loss Supplements”
 - Updated, detailed information about hepatic risks with kava
 - Information about kratom, an herb to avoid because of significant risks
 - Overview of piperine, an alkaloid found in black pepper that could affect certain medication pharmacodynamics/kinetics

- Chapter 52, “Common Complementary and Integrative Medicine Health Systems”
 - Focus change from complementary and alternative medicine (CAM) to complementary and integrative medicine (CIM)
- For all chapters that discuss disorders, development of new case studies in the comprehensive format

Chapter Features and Content

All chapters that discuss disorders in this edition include the following features and information:

- Up-to-date information on nonprescription medications, including indications, dosages, interactions, supportive evidence for efficacy and safety, medical disorders or symptoms amenable to self-treatment, prescription-to-nonprescription reclassifications, and nonprescription drug withdrawals from the market.
- Treatment algorithms that outline triage and treatment.
- Controversies in self-care therapeutics.
- Self-care treatment or prevention guidelines.
- Product tables with examples of specific nonprescription products.
- New nonprescription medications and dietary supplements, including nutrition-related dietary supplements, such as vitamins and minerals, which are discussed in the nutrition section of the book.

Most chapter features remain unchanged and are intended to promote an interactive approach to self-care. Students and health care providers can use these features to develop or improve problem-solving and critical thinking skills.

- Disorder-related chapters are grouped primarily according to body systems. These chapters begin with a discussion of the epidemiologic, etiologic, and pathophysiologic characteristics and the clinical manifestations of the disorder. These discussions are followed by a comprehensive discussion of self-care options. The inclusion of dietary supplements, as well as nonpharmacologic and preventive measures, completes the discussion of self-care options.
- Case studies, treatment algorithms, comparisons of self-treatments, patient education boxes, and product selection guidelines foster an interactive therapeutic approach to learning.
- Sections on the evaluation of patient outcomes reinforce follow-up of patients who are self-treating. This section defines the parameters for confirming successful self-treatment and those that indicate the need for medical referral.
- Chapters include tables that list interactions (drug–drug, drug–supplement, drug–nutrient), as well as dosage and administration guidelines.
- At the end of each chapter, authors provide a list of key points. These are intended to serve as a summary of critical information in the chapter and can be an excellent resource for educators.
- Authors provide comparisons of agents based on clinical studies of safety and efficacy, as well as product selection guidelines based on patient factors and preferences.
- Authors discuss the role of nonprescription therapies among the available treatment options for a specific disorder and describe other options in the event that nonprescription therapy fails or is not appropriate.

- The book's organization and content allow students and health care providers to quickly identify the information needed to make a treatment recommendation and to counsel patients.

Acknowledgments

We would like to acknowledge the hundreds of individuals who contributed to the new edition of this textbook. We are grateful to each of the authors and reviewers who contributed to this comprehensive and authoritative textbook. These individuals were selected from many practice settings and health professions throughout the country. Their scholarship and clinical experience reflect a broad perspective and interdisciplinary approach to patient care. The dedication of the authors and reviewers in ensuring that chapters were accurate, comprehensive, balanced, and relevant to practice and of the highest quality is deeply appreciated.

The editors of this edition also want to acknowledge the contributions of previous editors, authors, reviewers, and the many

health care providers, students, residents, and others who have helped make the *Handbook* the premier resource for self-care content. We also want to thank the staff of the American Pharmacists Association, in particular Julian Graubart, for their ongoing support of our vision for the content and its incorporation into the *Handbook* and PharmacyLibrary.com.

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We are confident that the combined efforts of these individuals will ensure that the *Handbook of Nonprescription Drugs: An Interactive Approach to Self-care* continues to serve as the worldwide practice and teaching resource on self-care and nonprescription products.

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