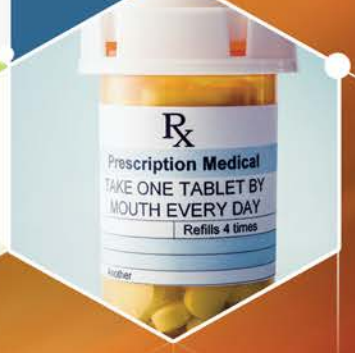
Essentials *of* Pharmacology *for* Health Professions

8th Edition



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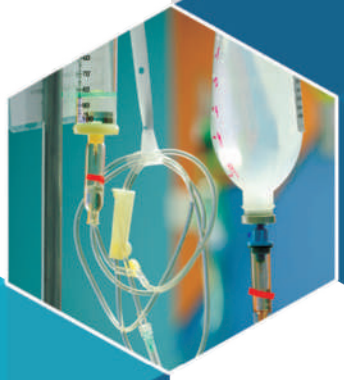

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Essentials of Pharmacology for Health Professions, Eighth Edition
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Dedication

To my loving wife Patty and two fantastic sons, Joshua and Jeremy. Also to Ali, a wonderful daughter-in-law and mother of our latest family addition, baby Lenyx. I'm truly blessed to have such a great family.

Bruce J. Colbert

To my grandchildren, Ashton, Jeff, Samantha, and Eric, may they realize that knowledge is power and seek to grow in knowledge and wisdom all of their lives.

Ruth Woodrow

Preface

This book is designed as:

- A basic text for learners studying nursing, medical assisting, and other health care professions.
- A continuing education update for professionals in health care.
- Part of a refresher program for professionals returning to health care professions.
- A supplemental or reference book for professionals wishing to extend their knowledge beyond basic training in specific health professions.

The purpose of this book is to provide an extensive framework of knowledge that can be acquired within a limited time frame. This book will be especially helpful for learners in one-year training programs with limited time allotted to the study of medications. For those in longer programs, it can be used as the basis for more extensive study. It is appropriate as a required text in training those who will administer medications. This book has been especially designed to meet the needs of learners in nursing and medical assistant programs. However, learners in all health care programs will also find the concise format adaptable to their needs.

This text has been field tested in several classes with learners in various health professions. Learners who have already used this book for updating or supplemental education include registered nurses, licensed practical nurses, medical assistants, surgical technologists, respiratory therapists, and pharmacy technicians.

Those employed in health professions now have increased responsibilities for providing the necessary information to their patients regarding the safe administration of medications, side effects, and interactions. Patient education is presented in every chapter in Part II. Even if you are not involved directly in patient education, it is imperative you understand what information is being conveyed.

ORGANIZATION

The quantity of information could be overwhelming and confusing to the learner unless presented in a reader friendly manner.

The book's comprehensive yet concise format reduces the massive quantity of information and unnecessary detail that may tend to overwhelm or confuse the learner. Outdated or rarely used medications, obsolete information, and complex descriptions are eliminated. The information is both factual and functional.

The textbook is broken down into two specific parts. ***Part I*** can stand alone as a basic but comprehensive review of pharmacologic principles. ***Part I*** introduces the learner to the fascinating subject of drugs, their sources, legal concerns, and their medical uses. *Review questions* at the end of each chapter help the learner master the information. Medication preparation, supplies, and specific information on each route of administration are covered. *Administration checklists* allow the learner to put the knowledge into practice. *Illustrations* and *videos* on the *online resources* facilitate the visual learning process.

Part II organizes the drugs according to classifications, arranged in logical order. Each classification is described, along with the characteristics of typical drugs, their purposes, side effects, precautions or contraindications, and interactions. Please note precautions and contraindications are combined as one category since it is clear from the explanation where the drug *is not to be used* in a certain situation (contraindication) and where it *can be used* in a certain situation but should be monitored closely (precautions). A special icon ! identifies the most common or most important side effects of drugs. This special icon is meant to serve as a valuable guide for learners. Rather than memorizing every side effect for each drug, the icon emphasizes the side effects with which health care professionals should be most familiar. *Patient education boxes* for each category are highlighted. These special boxes will assist health care professionals to educate patients and answer their questions about the medications they are taking.

Easy-to-use *reference tables* with each classification list the most commonly prescribed drugs according to their generic and trade names, with dosage and available forms.

Reality-based case studies in each chapter in Part II present drug usage scenarios in a variety of settings and stimulate critical thinking by providing practical application of drug information.

Chapter *review quizzes* assist learners to identify areas for further study. *Comprehensive review quizzes* for Part I and Part II encourage learners to practice for the final test.

An extensive *glossary* lists and defines key terms used in the book and defines non-key terms that might not be common knowledge such as unusual side effects. A comprehensive index includes both generic and trade names.

CHANGES TO THE EIGHTH EDITION

Global Textbook Changes

- Each drug classification was updated with the latest and most frequently prescribed drugs available.
- Tables were added and updated to give concise and practical information.

- Patient education boxes were expanded.
- A Clinical Connection feature was added to give a real-life application to the material being discussed to enhance its relevancy.
- Several new illustrations and photos were added to provide learners with a visual connection to the material.
- Additional art was updated to reflect the rapid changes in pharmacology.
- Review questions were updated and new questions were added to cover new material.
- The glossary was expanded to include new terms beyond just the key terms.

The following chapters in the text had significant additions with topics of current interest.

CHAPTER	SPECIFIC CHANGES IN TEXTBOOK
1	Added National Drug Code Directory (NDC) information Expansion of discussion on opioid overdose crisis Updated Controlled Substances Schedule Added medication labels and questions
2	Added discussion of Tall Man Lettering to differentiate look-alike and sound-alike drugs Added information of the Over-the Counter (OTC) Drug Advisory Committee
3	Discussed medications that crossed the blood–brain and fetal barriers Expanded therapeutic levels, metabolism, and drug interactions Added a Clinical Connection on narcotic overdose and treatment Expanded images and information on the Epipen and treatment of anaphylaxis
4	Updated IV images and terminology Updated needle information Expanded the transdermal delivery information Discussed implantable medication delivery devices
5	Computerized documentation updates were made, including computerized physician order entry (CPOE) and electronic medication administration records (eMAR) Expanded abbreviations for Medication Orders
6	Included a Clinical Connection on the use of reasoning to verify drug dosage calculations
7	Added information on confirming correct dosage forms Added a Clinical Connection on confirmation bias
8	Added information on aspiration Added eMAR information in relationship to medication administration Updated medication administration steps Added a Clinical Connection on patient education regarding suppositories
9	Added a new section on IV fluids Updated IV administration Added a Clinical Connection on proper medication patch disposal Provided updated information on insulin pens Added a Clinical Connection on site rotation for injections
10	Added a Clinical Connection on contrasting contacting poison control versus emergency services

11	Added a Clinical Connection on Warfarin and Vitamin K
	Added a new section on electrolytes and minerals
	Added a Clinical Connection on Calcium and Vitamin D
12	Updated the photo for oral thrush
	Added a photo for shingles
	Added updated treatment options for shingles
	Added a Clinical Connection on the Shingles vaccine
13	Added information concerning second dose with Epi-Pen
	Added a Clinical Connection on patient compliance with beta blockers
	Added a Clinical Connection on ophthalmic atropine
14	Added an illustration on cancer cell vs normal cell
	Added a photo of Gardasil/Ceravix
	Added extravasation to chemo side effects chart
	Added a Clinical Connection on Methotrexate dosing
	Added a Clinical Connection on Extravasation
15	Added an illustration on urinary tract infections
	Added an illustration on BPH (benign prostatic hyperplasia)
	Updated gout information
	Added a Clinical Connection on urinary tract infections
16	Added an illustration on peptic ulcer
	Added an illustration on *C. diff* and isolation
	Added a Clinical Connection on gastric and duodenal ulcers
	Updated information on diarrhea treatment
	Added a section on mu-opiod receptor antagonists for opioid-induced constipation (OIC)
17	Added the CDC immunization schedule for adults
	Added a Clinical Connection on the duration of antibiotic therapy
	Added information on Z-PAK dosing
	Added a Clinical Connection on Disulfuram-like reactions
18	Added a new section on ear medications
	Added information and an illustration on the anatomy of the ear
	Added a table on otic preparations
	Added a Clinical Connection on eye drops for ear drops
19	Added an illustration of the pain scale
	Added an image on cutting Lidocaine patches
	Added information on PRN dosing for pain versus maintenance dosing
	Added a Clinical Connection on opioid-induced constipation
	Added information on acetaminophen dosing and overdose
	Added information on medical marijuana
20	Added a photo on bipolar disorder
	Added an illustration on alcoholism
	Added information on ADHD treatment
	Added a Clinical Connection on racemic mixtures of drugs
	Added a section on proper disposal and storage of medications

21	Added a photo of Voltaren Gel
	Added an illustration of osteoporosis
	Added a new section on newer drugs for osteoporosis
	Added a new section on muscle relaxants
	Added a Clinical Connection on medication reconciliation
22	Added an illustration on seizures and how to handle them as a bystander
	Added an illustration detailing the symptoms of Parkinson's disease
	Added a Clinical Connection on driving with seizure-related conditions
23	Added illustrations on hypothyroidism and Grave's disease
	Added a corticosteroid equivalency table
	Added a chart on diabetes type I versus type II
	Added information on thyroid replacement dosing and adjustment
	Added a Clinical Connection on narrow therapeutic index drugs
	Added a section on SGLT2 Inhibitor therapy
24	Added an illustration detailing the symptoms of menopause
	Added a photo of oral birth control
	Added a Clinical Connection on deep vein thrombosis prevention
	Updated Plan B availability information
25	Added an illustration on heart failure
	Added a Clinical Connection on patient information interviews
	Added information on INR and warfarin dosing
26	Added a section on cleaning MDI's
	Added a Clinical Connection on rescue inhaler use
	Added information on rinsing the mouth after using inhaled corticosteroids
	Added information on dextromethorphan use in children
	Added information on pseudoephedrine purchasing limits
27	Added photos to illustrate how pill boxes can be used as memory aids for older adults
	Added information on "LOT" benzodiazepines for older adults
	Added a Clinical Connection on the other end of the spectrum
	Added a section on MTM and CMRs to combat polypharmacy
	Added a section on adherence in older adults

STUDENT RESOURCES

Study Guide

The Study Guide offers additional practice with review questions corresponding to each chapter in the text, including multiple choice, fill-in-the-blank, true or false, and matching questions. Case studies encourage students to apply the knowledge learned in Part II about drugs.

Online Resources

Online resources are available to enhance the learning experience. Additional resources include:

- "Treatment of the Opportunistic Infections of AIDS" content
- Medication administration videos that allow learners to "see" concepts in action
- Slide presentations in PowerPoint®

Accessing the online resources:

1. Go to http://www.cengagebrain.com.
2. Register as a new user or log in as an existing user if you already have an account with Cengage Learning or cengagebrain.com.
3. Select **Go to MY Account.**
4. Open the product from the My Account page.

INSTRUCTOR RESOURCES

Learning Lab

The Learning Lab is an **online homework solution** that allows your students to practice the most difficult concepts associated with their Cengage Learning textbooks in a simulated real-world environment.

Developed to help you improve program quality and retention, the Learning Lab prepares your students for their career by *increasing comprehension and critical thinking skills.*

Instructor Companion Site

Powerful resources for instructors are available to assist you with teaching pharmacology, assessing your students' mastery of the material, and elevating students' learning.

- **Cognero online test bank** makes generating tests and quizzes a snap. With over 1,300 questions in a variety of formats to choose from, you can create customized assessments for your students with the click of a button. Adding your own unique questions has never been easier.
  - Also included with the Cognero online test bank are over 500 **NCLEX-style questions.**
- Customizable instructor slide presentations created in **PowerPoint**, including images, focus on the key concepts from each chapter. Medication administration videos that allow learners to "see" concepts in action are available for students on the online resources.

- Electronic Instructor's Manual includes the following tools:
  - Additional review quizzes with answers
  - Comprehensive drug worksheets with answers
  - An alternate Comprehensive Exam for Part II with answers
  - Answers to review quizzes and comprehensive review exams in the text
  - Answers to case studies in Part II in the text
  - Answers to review questions and case studies in the Study Guide

MINDTAP

MindTap is a fully online, interactive learning experience built upon authoritative Cengage Learning content. By combining readings, multimedia, activities, and assessments into a singular learning path, MindTap elevates learning by providing real-world application to better engage students. Instructors customize the learning path by selecting Cengage Learning resources and adding their own content via apps that integrate into the MindTap framework seamlessly with many learning management systems.

The guided learning path demonstrates the relevance of basic pharmacology principles to health care professions through engagement activities, interactive exercises, and procedural videos. The Pronounce activity ensures correct pronunciation of the top 200 drugs, plus additional hospital drugs. Easy-to-use *reference tables* with each classification list the most commonly prescribed drugs according to their generic and trade names, with dosage and available forms, special considerations, and audio to encourage correct pronunciation of the drugs most likely to be encountered in health care. Learners apply an understanding of pharmacology through patient education scenarios. These simulations elevate the study of pharmacology by challenging students to apply concepts to practice.

To learn more, visit www.cengage.com/mindtap.

TO THE LEARNER STUDYING PHARMACOLOGY

Other learners such as you have helped me put this book together. They have learned that the study of medications can be a fascinating one. They have told me that this book has helped them to develop confidence and competence in dispensing medications and sharing information about drugs with their patients. You will find this is only the beginning, a framework upon which you will build a vast store of useful knowledge.

Learners have told me that the objectives, review questions, and case studies were tremendously helpful to them. Organization is the key to acquiring large quantities of information. You will be amazed at all you have learned when you complete this book.

Keep growing and learning and questioning all of your life.

Ruth Woodrow

ACKNOWLEDGMENTS

There are a lot of people to thank in a project of this scope. First and foremost, I would like to thank Ruth Woodrow for her dedication to helping students learn. It is an honor to continue to work on such a quality textbook and with such an inspiring author who maintains her passion for learning, teaching, mentoring, and volunteerism. She truly lives her values and continues to imprint her knowledge and dedication to presenting an engaging, meaningful, and readable pharmacology textbook.

I would also like to thank Adam James who served as the pharmacist consultant on this project to make sure we got it right. I have known Adam for several years and I'm very impressed with his work ethic, knowledge, and professionalism. His updates with the latest and greatest information concerning specific drugs and dosages have been truly appreciated.

Liz Katrancha deserves a big thank you for being the nursing consultant to make sure we keep the project patient centered, clinically applied and up-to-date. I have had the pleasure of working with Liz on several projects and her attention to detail and quality of work are greatly appreciated.

My first editor Matt Seeley deserves a very large thank you for considering me in the first place and believing in me for this project. I also appreciate his forward thinking in adding enhanced digital experiences to an already successful textbook. My current editor Laura Stewart deserves much praise for her dedication in moving this project forward, especially in the digital realms. In addition, she has made the transition a very smooth and pleasant one.

Last but certainly not least, I want to personally thank Debra Myette-Flis, for her tremendous assistance, organizational skills, professional knowledge, and guidance in helping to make this project a joy on which to work. Deb quietly does so much "behind-the-scenes" work that I wanted to especially acknowledge and express my appreciation for keeping me on track and her focus on making this project the best it can be.

Bruce J. Colbert

I would like to acknowledge the support, encouragement, and technical assistance of my husband, Roger.

I am grateful to Bruce Colbert, a dedicated teacher and author, for taking over the edition revisions. Bruce shares my empathy for the student and the ideal of keeping it simple for successful learning. In addition, he continues to share his creative ideas for incorporating technology to enhance the learning experience. A big thanks to Bruce for keeping me involved.

I wish to thank all of those at Cengage Learning who contributed in any way to this text. Appreciation is expressed particularly to Debra Myette-Flis, senior content developer, for all of her guidance and support throughout the editions and

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Ruth Woodrow

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PART 1

Introduction to Pharmacologic Principles

CHAPTER 1

CONSUMER SAFETY AND DRUG REGULATIONS

KEY TERMS AND CONCEPTS

Controlled substances
Drug Enforcement Administration (DEA)
Drug standards
Food and Drug Administration (FDA)
National Drug Code (NDC) Directory
Orphan drugs
Over-the-counter (OTC) medication

OBJECTIVES

Upon completion of this chapter, the learner should be able to

1. Explain what is meant by drug standards
2. Name the first drug law passed in the United States for consumer safety, and give the year it was passed
3. Summarize the provisions of the Federal Food, Drug, and Cosmetic Act of 1938, and identify the government agency that enforces the act
4. Interpret what is meant by USP/NF
5. Summarize the provisions of the Controlled Substances Act of 1970
6. Explain what is meant by a DEA number and the NDC Directory
7. Define schedules of controlled substances, and differentiate between C-I through C-V schedules
8. State several responsibilities you have in administering medications as a direct result of the three major drug laws described in this chapter
9. Define the Key Terms and Concepts

Your decision to pursue a career in the health care field probably took a great deal of thought. No doubt you have questioned whether you will be able to handle the unique situations that arise in a clinic, health care facility, or physician's office. Have you ever stopped to consider the impact *you* will make on the lives of others as a health care professional? Not only can you make a tremendous difference in the facility where you work, but you can also have a positive impact on your friends and family, as well as the patient or client.

It is inevitable that you will receive phone calls and questions about medications, prescriptions, and drug therapy. A great majority of patients are far too inhibited to tell their physicians that there are things they do not understand about their medications. They feel much more at ease discussing their questions with health

care professionals. Your potential for informing others with knowledgeable answers about medications can be quite an asset!

The key to reaching that potential is having knowledgeable answers coupled with a serious, responsible attitude about all aspects of drug therapy. Consider yourself a potential prime resource of medication information for your friends, family, and future patients as you begin to examine the foundations of facts about drugs. It may be necessary for you to clarify some of the layperson misunderstandings about the legalities of dispensing medications. Consider the following misconceptions and facts.

Fallacy	Fact
Only nurses can give medications to patients.	Trained and certified health care professionals who may legally give medications include physicians; physician assistants; paramedics; medical office assistants; unlicensed assistive personnel; practical, vocational, and registered nurses; and other allied health specialists such as respiratory therapists and pharmacists.
Only physicians may write prescriptions.	Dentists, physicians, physician assistants, veterinarians, nurse practitioners, and registered pharmacists may write prescriptions for their specific field of work, as governed by state law. For example, veterinarians write prescriptions only for animal use.
Prescriptions are required for narcotics only.	Specific drugs ruled illegal to purchase without the use of a prescription include the following: • Those that need to be controlled *because they are addictive and tend to be abused and dangerous* (e.g., depressants, stimulants, psychedelics, and narcotics). • Those that may cause dangerous health threats from side effects if taken incorrectly (e.g., antibiotics, cardiac drugs, and tranquilizers).
All drugs produced in the United States are made in federally approved laboratories.	Numerous illegal laboratories that produce illicit substances such as methamphetamines exist and operate within the United States today.
All herbal medicines and dietary supplements are safe.	Herbal remedies and other dietary supplements are not approved or manufactured per production standards regulated by the Food and Drug Administration (FDA) and may have serious interactions with prescribed medications. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market and against marketed products that make false or misleading claims. (See Chapter 11.)

DRUG LAWS

Individuals have been using substances and drugs for healing purposes for centuries. Due to scientific advances and changes in our society in the last century, consumer safety has become a critical issue. During the 1900s, laws were passed that specifically addressed the matter of dispensing drugs in the United States.

Drug standards are rules set to assure consumers that they get what they pay for. The law says that all preparations called by the same drug name must be of *uniform strength*, *quality*, and *purity*.

Because of drug standardization, when you take a prescription to be filled, you are assured of getting the same basic drug, in the same amount and quality, regardless of the pharmacy or the part of the country where you take the prescription. According to drug standards, the drug companies must not add other active ingredients or varying amounts of chemicals to a specific drug preparation. They must meet the drug

standards (federally approved requirements) for the specified strength, quality, and purity of the drug.

In the market of illegal (illicit) drugs, the lack of enforcement of drug standards poses danger to the consumer. With no controls on the quality of illegal drugs, many deaths have occurred from overdose. Consider the heroin user, accustomed to very poor-quality heroin, who accidentally overdoses when given a much higher quality of heroin from a new source. In general, across the country, opioid and other drug overdoses have become a major problem. This will be highlighted throughout following chapters, but it is important to be aware of the problems that can arise when certain drugs are abused.

The laws that have evolved to provide consumer safety can be summed up by three major acts. They are described in the order they became necessary for consumer safety, beginning with the 1906 Pure Food and Drug Act.

1906 PURE FOOD AND DRUG ACT

First government attempt to establish consumer protection in the manufacture of drugs and foods.

Required all drugs marketed in the United States to meet minimal standards of strength, purity, and quality.

Demanded that drug preparations containing dangerous ingredients have a labeled container indicating the ingredient. Originally there were 11 "dangerous" ingredients, such as morphine.

Established two references of *officially* approved drugs. Before 1906, information about drugs was handed down from generation to generation. No official written resources existed. After the 1906 legislation, two references specified the official U.S. standards for making each drug. These references, listed here, have since been combined into one book, referred to as the *USP/NF*:

- *United States Pharmacopeia (USP)*
- *National Formulary (NF)*

The importance of the timing of the 1938 Federal Food, Drug, and Cosmetic Act should be noted. It came about as the answer to a disastrous occurrence in 1937. A sulfa preparation, not adequately tested for safety, was responsible for 100 deaths that year. Thus, the need was recognized for more proof of the safety of new drugs.

1938 FEDERAL FOOD, DRUG, AND COSMETIC ACT AND AMENDMENTS OF 1951,1962, AND 1972

Established the Food and Drug Administration (FDA) under the Department of Health and Human Services to enforce the provisions of the act.

Established *more specific* regulations to prevent adulteration of (tampering with) drugs, foods, and cosmetics:

- All labels must be accurate and must include a listing of all active and inactive ingredients. Figure 1-1 shows an example of required product information for an over-the-counter (OTC) medication (no prescription [Rx] needed).
- All new products must be approved by the FDA before public release.
- "Warning" labels must be present on certain preparations, for example, "may cause drowsiness," "may cause nervousness," and "may be habit-forming."
- Certain drugs must be labeled with the legend (inscription): "Caution—federal law prohibits dispensing without a prescription." Thus, the term *legend drug* refers to such preparations. The act also designated which drugs can be sold without a prescription.
- Prescription and nonprescription drugs must be shown to be *effective* as well as *safe*.
- In 1972, the National Drug Code (NDC) Directory was established. This provided the FDA with a list of all drugs manufactured for commercial distribution. Each drug is identified by an NDC number, made up of three parts (see Figure 1-2).
  - The first part is five numbers and identifies the manufacturer.
  - The second part is four numbers and identifies the drug.
  - The third part is two digits and identifies the package size.
    - Example: 00406-0123-01; note it is a common practice to omit a leading zero in the first or second part of the NDC number so this drug could also be written as 0406-123-01.

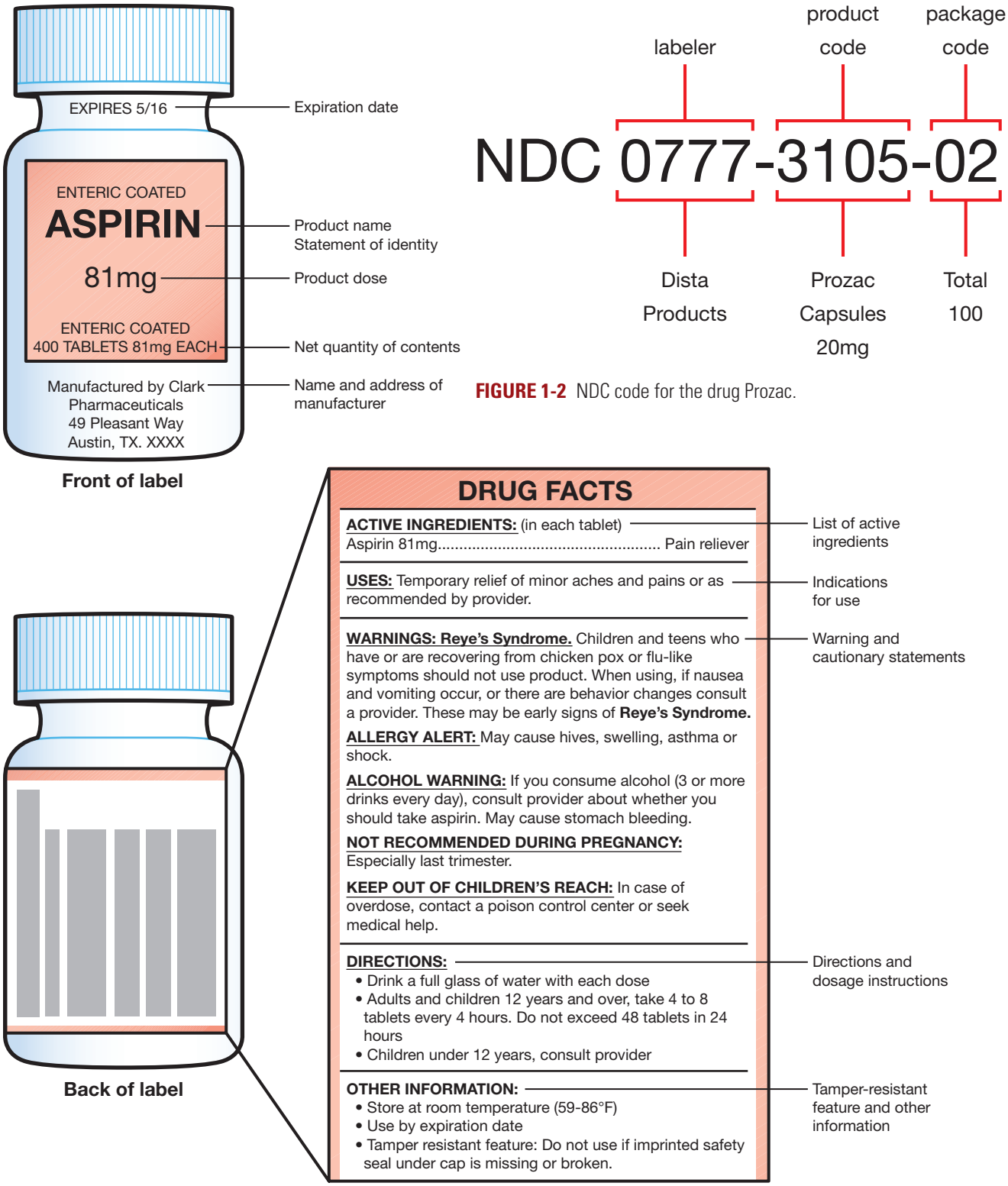


FIGURE 1-1 Consumer medication labels contain valuable information for safe and effective use of the drug.

FIGURE 1-2 NDC code for the drug Prozac.

The five schedules of controlled substances are arranged with those with the highest potential for abuse at level I and those with the least abuse potential at level V. It should be noted that even those drugs in class level V have more potential for abuse than most drugs. Additionally, the lower the number, the stricter are the restrictions for control by the DEA. Therefore, it makes sense that Schedule I drugs are illegal and are not approved for medicinal purposes in the United States.

Drugs are frequently added, deleted, or moved from one schedule to another. If, for example, the DEA determines that drug A is becoming more of a societal problem, with an increased incidence of overdoses, drug A may be moved from the C-IV schedule to C-III. It is extremely important that the health care professional keep informed of any changes in drug scheduling. For the most part, using the most current drug reference book will keep you up to date.

You will recognize the schedule of a particular controlled substance by noting a *C* with either *I, II, III, IV,* or *V* after it. Some references show the capital C with the Roman numeral inside the curve of the C (Ⓒ). Labels on controlled substances are also designated with a C and a Roman numeral to indicate their level of control. Drug inserts (information leaflets accompanying drugs) are also marked with a C and the appropriate schedule number. (See Table 1-1 and Figure 1-3.)

1970 CONTROLLED SUBSTANCES ACT

Established the Drug Enforcement Administration (DEA) as a bureau of the Department of Justice to enforce the provisions of the act.

Set much tighter controls on a specific group of drugs: *those that were being abused by society*; the name of the act indicates that such *substances needed to be controlled.* These substances include depressants, stimulants, psychedelics, narcotics, and anabolic steroids. The act:

- Isolated the abused and addicting drugs into five levels, or schedules, according to their medical value, harmfulness, and potential for abuse or addiction: C-I, C-II, C-III, C-IV, and C-V.
- Demanded security and accountability of controlled substances; anyone (e.g., pharmacists, hospitals, physicians, and drug companies) who dispenses, receives, sells, or destroys controlled substances must keep on hand special DEA forms, indicating the exact current inventory and a two-year inventory of every controlled substance transaction.
- Set limitations on the use of prescriptions; guidelines were established for each of the five schedules of controlled substances, regulating the number of times a drug may be prescribed in a six-month period as well as for which schedules prescriptions may be phoned in to the pharmacy and so on.
- Demanded that each prescriber of these substances register with the DEA and obtain a DEA registration number, to be present on their prescriptions of controlled substances; drug manufacturers must also be registered and identified with their own DEA numbers, as must pharmacists, physicians, veterinarians, and so on.

MEDIALINK

See It in Action! View a video on *Managing Controlled Substances* on the Online Resources.

Although many other drug laws exist, there are two significant pieces of drug legislation that are important to mention here. The 1983 Orphan Drug Act gives pharmaceutical companies financial incentives to develop medications for diseases that affect only a small number of people. This encourages the companies to develop **orphan drugs** that would otherwise be of low profitability. The other legislation is the strangely named Omnibus Budget Reconciliation Act (OBRA) of 1990. This act mandates that all OTC drugs a patient is taking must be documented as part of the medical record. OBRA also mandates that pharmacists provide drug use review and patient counseling before dispensing prescriptions to a patient.

TABLE 1-1 Five Schedules of Controlled Substances

SCHEDULE NUMBER	ABUSE POTENTIAL AND LEGAL LIMITATIONS	EXAMPLES OF SUBSTANCES
1, Ⓒ	High abuse potential Not approved for medical use in the United States	Heroin, LSD, mescaline, ecstasy
2, ⒸⅡ	High abuse potential May lead to severe dependence Written prescription only (or electronic prescriptions that meet DEA standards) No phoning in of prescription by the office health care professional, in an emergency, physician may phone in, but handwritten prescription must go to the pharmacy within seven days No refills without new written prescription Prescription may be faxed, but original prescription must be handed in to pick up prescription	Morphine, codeine, methadone, Percocet, Dilaudid, Ritalin, Oxycontin, meperidine (Demerol), Hydrocodone with Tylenol
3, ⒸⅢ	May lead to moderate dependence Written, faxed, or verbal (phoned in) prescription, by physician only May be refilled up to five times in six months	Codeine and, anabolic (muscle-building) steroids
4, ⒸⅣ	Lower abuse potential than the previous schedules Prescription may be written out by the health care professional but must be signed by the physician Prescription may be phoned in by the health care professional or faxed May be refilled up to five times in six months	Valium, Ativan, Xanax, phenobarbital, Librium, Restoril, and Ambien
5, Ⓒ Ⅴ	Low abuse potential compared to the previous schedules Consists primarily of preparations for cough suppressants containing codeine and preparations for diarrhea (e.g., diphenoxylate) May be refilled up to five times in six months	Promethazine with codeine, Cheratussin AC, Lomotil

Note: Some states may have stricter schedules than the federal regulations. You must be aware of the regulations in your area.

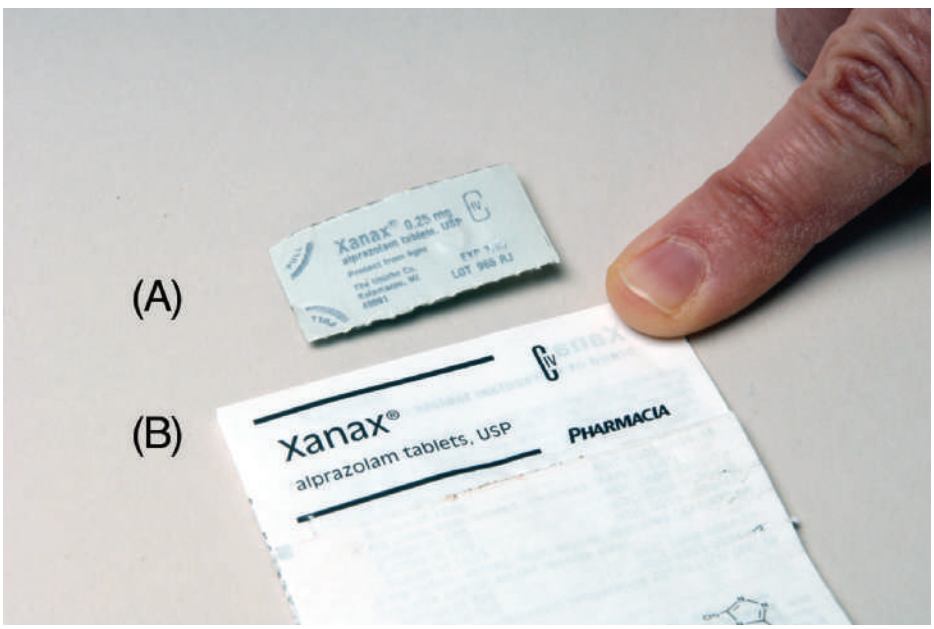


FIGURE 1-3 Controlled substance schedule numbers appear in a variety of drug information resources, including (A) drug packages and (B) drug inserts. Schedule numbers are also found in drug reference sources.

FDA AND DEA

The increase in the number of drugs produced for marketing brought dangers to the public. The federal FDA was established to ensure that some basic standards would be followed. Its responsibilities include:

- Overseeing testing of all proposed new drugs before they are released into the U.S. market
- Inspecting plants where foods, drugs, medical devices, or cosmetics are made
- Reviewing new drug applications and petitions for food additives
- Investigating and removing unsafe drugs from the market
- Ensuring proper labeling of foods, cosmetics, and drugs

When the need for better control of addictive drugs became urgent, the FDA had its hands full just trying to enforce basic drug standards. It became imperative to set up a new department, the DEA, in 1970 to handle all the needs and safety controls for the more dangerous drugs. Thus, the two agencies—FDA and DEA—were established with their own specific areas of drug control.

As a health care professional and an informed citizen, you must be aware of the latest developments concerning these two agencies. Hardly a week goes by without mention of the activities of the FDA or the DEA in the news. You should be able to recognize their separate areas of control.

FDA

Concerned with general safety standards in the production of drugs, foods, and cosmetics.

Responsible for approval and removal of products on the market.

Special note on drug withdrawals: In rare cases, the FDA may need to reassess and change its approval decision on a drug. A conclusion that a drug should no longer be marketed is based on the nature and frequency of the adverse events and how the drug's benefit and risk balance compares with treatment alternatives. When the FDA believes that a drug's benefits no longer outweigh its risks, the agency will ask the manufacturer to withdraw the drug. Interestingly, the FDA does not have the legal authority to withdraw a marketed drug product itself.

DEA

Concerned only with controlled substances.

Enforces laws against drug activities, including illegal drug use, dealing, and manufacturing.

Monitors need for changing the schedules of abused drugs.

HEALTH CARE PROFESSIONALS AND THE LAW AND ETHICS

In some ways, you will be as involved as the physician in observing the restrictions of the drug laws. You will have the responsibility of keeping accurate records of the medications dispensed. You will maintain the supply of drugs at your facility. If you work in a physician's office, a clinic, or an ambulatory care setting, you will also

be involved with phoning in prescriptions and securing prescription forms at your facility. You must act ethically to ensure that the ordered medications are given in the appropriate amount to the appropriate patient.

The following guidelines should be followed by the health care professional involved in dispensing medications:

1. Keep a *current* drug reference source available at all times. You should be able to readily identify substances that are controlled by the DEA.
2. Keep controlled substances locked securely. Double-locking is required in most situations. This means:
   a. Placing the drugs in a locked safety box.
   b. Placing the locked box in a cupboard that is also locked.
3. Conceal and secure prescription pads at your office, clinic, or facility. Do not leave pads out in the open, especially in patient examining rooms. The prescription pads, with the physician's DEA registration number, are a possible source of fraud and drug tampering when forged and used illegally. Keep the pads locked up and in a designated location (e.g., a drawer), out of the public areas of the office or nursing station. One of the most common ways prescriptions are forged is through a stolen prescription pad.
4. Keep accurate records of each controlled substance administered, received, or destroyed at your facility. These records, as well as the records from the previous two years, must be available at all times. Properly destroy expired drugs and old records.
5. Be responsible for keeping up to date with current news of the activities of the FDA and the DEA. If working for a physician, monitor the DEA registration renewal date. Keep informed of any changes in the scheduling of controlled substances.
6. Establish a working rapport with a pharmacist. A local pharmacist is an excellent resource for you when you are unsure of your legal responsibilities with drugs or have any uncertainties about drug therapy.
7. If you work in an office, maintain a professional rapport with the pharmaceutical representatives who leave drug samples there. As part of the Affordable Care Act, the Sunshine Act now requires reporting of compensation and gifts paid to physicians by pharmaceutical representatives. It is important that you are aware of the ethical dilemma that may occur when a physician is "rewarded" or compensated for prescribing certain medications.

CHAPTER REVIEW QUIZ

Complete the following statements

1. The first major U.S. drug law was passed in the year _____ and was called the _____.
2. USP stands for _____.
3. NF stands for _____.
4. Which drug law established the USP and NF (which are now one)? _____.
5. The agency that requires you to keep a record of each controlled substance transaction is the _____.
6. Prescriptions for schedule C-_____ drugs may be phoned in by the health care professional.
7. How long must you keep an inventory record of each controlled substance transaction at your office? _____.
8. Three responsibilities of the FDA include:

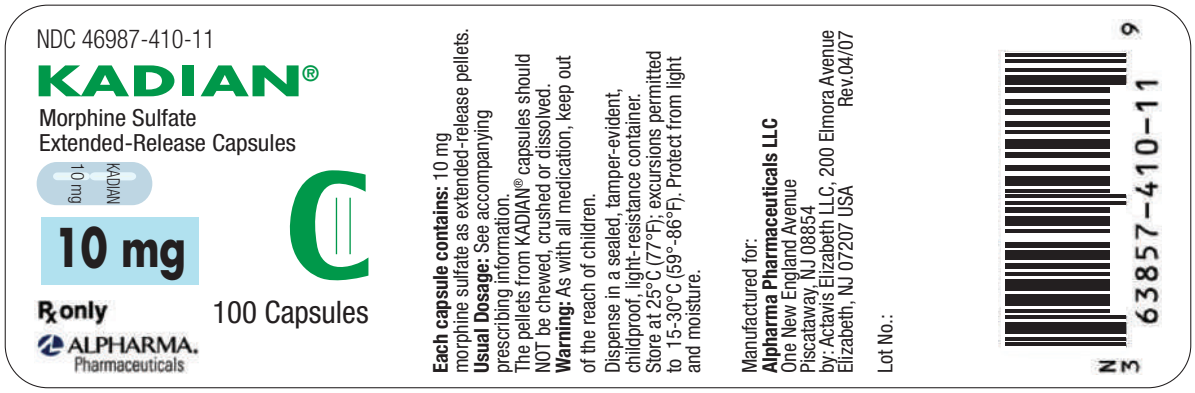
   _____

   _____

   _____
9. What types of drugs are listed in the C-V schedule? _____.
10. What method is recommended for securing the controlled substances at your office? _____.
11. If a patient calls to request a refill of a Percocet (C-II) prescription, how would you reply? _____.
12. Dawn Vasquez has a rare disease that requires medication for only a small population of patients. Which act has allowed her drug to be produced even though it is not profitable to the pharmaceutical industry? _____.
13. A patient calls into the office asking for a new prescription for a narcotic medication that he has been taking for six months. You bring up his chart and notice that he has been requesting new prescriptions every 23 days, whereas the medication should last 30 days. Additionally, the patient also mentions that he feels that he is in need of a higher dose and gets agitated and irritable when you tell him that he will need an appointment. What do you think of this? What should you do?
14. Answer the questions concerning the following three drug labels on the next page.
    a. Which drug(s) requires a prescription?
    b. Which drug(s) can be bought without a prescription?
    c. Which drug(s) requires a DEA number?

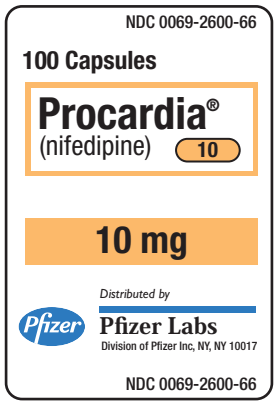
McNeil Consumer & Specialty Pharmaceuticals.

(A)



Used with permission from ALPHARMA Pharmaceuticals.

(B)



Used with permission from Pfizer, Inc.

(C)

STUDYGUIDE

PRACTICE

Complete Chapter 1

Online Resources

- Powerpoint presentations
- Videos

CHAPTER 2
DRUG NAMES AND REFERENCES

KEY TERMS AND CONCEPTS

Actions
Adverse reactions
Cautions
Classifications
Contraindications
Generic names
Indications
Interactions
Legend drug
Official name
Pharmacology
Prototype
Side effects
Tall Man Lettering
Trade names

OBJECTIVES

Upon completion of this chapter, the learner should be able to

1. Describe drug classification systems
2. Differentiate among the following drug names: generic name, official name, trade name, and chemical name
3. Explain what is indicated by a number included in a drug trade name (e.g., Tylenol No. 3)
4. Contrast generic and brand name drugs
5. Define and explain the restrictions of drug sales implied by the following: over-the-counter (OTC) drug, legend drug, and controlled substance
6. Discuss the various terms indicating drug actions contained in reference sources
7. List and describe at least two drug references available today
8. Discuss several characteristics that you consider important in choosing the best drug reference
9. Describe how to evaluate drug information websites
10. Define the Key Terms and Concepts

Pharmacology can be defined as the study of drugs and their origin, nature, properties, and effects on living organisms. We need to know why drugs are given, how they work, and what effects to expect. The thousands of drug products on the market would make this subject difficult to tackle if it were not for:

- Numerous drug references, geared to a variety of levels of readers, from layperson to pharmacist
- Grouping of drugs under broad subcategories
- Continuity in the use of basic identifying terms for the names and actions of drugs

CLASSIFICATIONS

Each drug can be categorized under a broad *subcategory*, or *subcategories*, called **classifications**. Although drugs can be classified in several different ways, grouping them together according to their therapeutic use is most helpful to the health care professional. Drugs that affect the body in similar ways are listed in the same classification. Drugs that have several types of therapeutic effects fit under several classifications. For example, aspirin has a variety of effects on the body. It may be given to relieve pain (analgesic), to reduce fever (antipyretic), to reduce inflammation of tissues (anti-inflammatory), or as an anti-platelet (anti-thrombotic agent). Therefore, aspirin is categorized under four classifications of drugs (as shown in parentheses).

Another drug, cyclobenzaprine (Flexeril), however, is known to be used for only one therapeutic effect: to relieve muscle spasms. Flexeril, therefore, is listed only under the one classification of muscle relaxant.

Examples of some common drug classifications are listed in Table 2-1. Are you familiar with any of them already?

The second part of this text compares the characteristics of the various major drug classifications. In each chapter, as a classification is explained, you will learn what general information to associate with drugs of that classification, including:

- Therapeutic uses
- Most common side effects
- Precautions to be used
- Contraindications (when *not* to use the drug)
- Interactions that may occur when taken with other drugs or foods
- Some of the most common product names, their usual dosages, and comments on administration

You may also be given a **prototype** of each drug classification. A prototype is a *model example*, a drug that typifies the characteristics of that classification. For example, propranolol (Inderal) is the prototype of the beta-adrenergic blockers (see Chapter 13).

TABLE 2-1 **Top 10 Drug Classifications and Examples**

CLASSIFICATION	THERAPEUTIC USE	DRUG EXAMPLE(S)
1) Lipid-lowering agents	Lowers low-density lipoprotein (LDL) cholesterol	simvastatin, atorvastatin, rosuvastatin
2) Antidepressants	Improves symptoms of depression. Also used for anxiety and other neurological disorders	escitalopram, sertraline, paroxetine, venlafaxine
3) Narcotic analgesics	Relieve severe pain	hydrocodone with acetaminophen, oxycodone, oxymorphone, fentanyl
4) Beta blockers	Lowers heart rate and blood pressure	metoprolol, atenolol, propranolol
5) Antihypertensives	Lowers blood pressure	lisinopril, enalapril, valsartan

(*continued*)

TABLE 2-1 **Top 10 Drug Classifications and Examples (*continued*)**

CLASSIFICATION	THERAPEUTIC USE	DRUG EXAMPLE(S)
6) Diuretics	Increases urinary output	furosemide
7) Antidiabetics	Reduces blood glucose (sugar) levels	insulin, metformin, glipizide, Januvia
8) Antibiotics	Eliminates infection	amoxicillin, cephalexin, doxycycline
9) Proton pump inhibitors	Decreases acidity of stomach	omeprazole, pantoprazole, esomeprazole
10) Anticoagulants	Decreases clotting in blood	warfarin, Xarelto

You can find the classification as well as the various names of a drug by referring to a drug reference source.

IDENTIFYING NAMES

Drug names can seem very complicated because a single drug will have many names attached to it. Four specific names can apply to each approved drug:

1. ***Generic name***.
   a. Common or general name assigned to the drug by the United States Adopted Name (USAN) council
   b. Differentiated from the trade name by initial lowercase letter
   c. Never capitalized
2. ***Trade name*** (also known as proprietary or brand name since owned by company).
   a. The name by which a pharmaceutical company identifies its product
   b. Copyrighted and used exclusively by that company
   c. Distinguished from the generic name by capitalized first letter
   d. Often shown on labels and references with the symbol ® after the name (for "registered" trademark)
3. ***Chemical name***.
   a. The exact molecular formula of the drug
   b. Usually a long, very difficult name to pronounce
   c. Of little concern to the health care professional
4. ***Official name***.
   a. Name of the drug as it appears in the official reference, the *United States Pharmacopeia/National Formulary (USP/NF)*
   b. Generally, the same as the generic name

The use of **generic names** and **trade names** for drugs can be compared to the various names of grocery products. Two examples of generic names are orange juice and detergent. Corresponding trade names for orange juice are Tropicana and Minute Maid, whereas Cheer and Tide are trade names for detergents. Although there is only one generic name, there may be many trade names.

When a company produces a new drug for the market, it assigns a generic name to the product. After testing and approval by the Food and Drug Administration (FDA),

the drug company gives the drug a trade name (often something short and easy to remember when advertised). For five years, from the time the company submits a *new drug application (NDA)* to the FDA for approval, the company has the exclusive right to market the drug. Once approved, the drug is listed in the *USP/NF* by an **official name**, which is usually the same as the generic name. After five years have passed and the patent has expired (although patent extensions are requested and frequently granted), other companies may begin to combine the same chemicals to form that specific generic product for marketing. Each company will assign its own specific trade name to the product, or the drug can be offered simply by its generic name and strength, such as acetaminophen 325 mg. See Table 2-2, which compares the names for two drugs.

TABLE 2-2 **Comparison of Drug Names**

GENERIC NAME	CHEMICAL NAME	TRADE NAMES (DRUG COMPANY)
doxycycline hyclate	2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, (4S,4aR,5S,5aR,6R,12aS)-(564-25-0)	Vibramycin (PD-RX Pharmaceuticals) doxycyclinehyclate[a] (West-Ward)
chlordiazepoxide hydrochloride	7-chloro-2 methylamino-5 phenyl-3H-1,4-benzodiazephine 4-oxide hydrochloride	Librium

[a]Some companies simply elect to market the product by the generic name.

Concerning prescription drugs, most states have enacted legislation encouraging physicians to let pharmacists substitute less expensive *generic equivalents* for prescribed brand name drugs. Specific provisions of drug *substitution laws* vary from state to state.

The physician may indicate "no substitutions" on the prescription, usually indicated by a *dispense as written (DAW) order*. Often physicians have preferences for certain products or patients may be difficult to stabilize on a certain class of medications (such as thyroid preparations). Even though the drug contents are the same, the "fillers," or ingredients that are used to hold the preparation together, may be slightly different. This difference in fillers may affect how quickly the drug dissolves or takes effect. Dyes in some products may alter effects in some sensitive patients by leading to an allergic response.

Many products are combinations of several generic components. You will recognize this when you see several generic names (not capitalized) and their corresponding amounts listed under one trade name (capitalized). Examples are given in Table 2-3.

TABLE 2-3 **Examples of Combination Drugs**

TRADE NAME	GENERIC NAME AND AMOUNT
Dyazide (used to treat high blood pressure)	hydrochlorothiazide 25 mg/triamterene 37.5 mg
Glucovance (used to treat Type 2 diabetes mellitus)	glyburide 1.25 mg/metformin 250 mg glyburide 2.5 mg/metformin 500 mg glyburide 5 mg/metformin 500 mg
Robitussin DM 5 mL syrup	dextromethorphan10 mg/guaifenesin, 100 mg

PATIENT EDUCATION

Patients may ask you about the difference between generic and trade (brand) name products. The FDA regulates the manufacturing of generic drugs, so patients can be assured that they are safe and cost-effective alternatives. Generally, trade name products are more expensive, although the basic active ingredients (drug contents) are the same as those in the generic. The higher price helps to pay for the costs of drug development and advertisements promoting the trade name. (Can you think of certain trade names that are heavily advertised in television commercials?)

Because generic drug equivalents may exist for both prescription and OTC drug products, it is often economically wise to check for medicines that have the same generic components and strengths. For example, several cough syrups may have exactly the same contents, but the prices may vary widely.

Read and compare all ingredients on the labels.

It should be noted that a number may be part of the trade name. The number often refers to an amount of one of the generic components and helps to differentiate it from an almost identical product. Identify the significance of the numbers in comparing the following trade names:

Trade Name	Generic Name and Amount
Tylenol No. 2	acetaminophen 300 mg codeine 15 mg
Tylenol No. 3	acetaminophen 300 mg codeine 30 mg
Tylenol No. 4	acetaminophen 300 mg codeine 60 mg

Note that each product contains the same amount of acetaminophen, with varying amounts of the controlled substance codeine. *The larger the number in the name, the greater is the amount of controlled substance present.*

Many drug errors have occurred because the trade name was misinterpreted for the number of tablets to be given. So . . .

Be certain you can clearly read and understand the order!

Another type of drug error involves preventable allergic reactions to one of the generic components of a medication. The problem stems from:

- Not consulting the patient's chart for the history of allergies before a new medication is ordered or given
- Not checking a reference to find out if a medication being ordered or given contains any generic components to which the patient has a known allergy

For example, if a patient has an allergy to aspirin, do not administer the first dose of any new medication to the patient without finding out if the product contains aspirin. Although the physician is in error for ordering the medication, you are also in error for administering a medication with which you are unfamiliar. A proficient health care professional should check the history and chart for known allergies and pick up any discrepancies. Alertness is the key to safety in any setting.

According to the Institute for Safe Medication Practices (ISMP) and the FDA, look-alike and sound-alike medications are a leading cause of drug errors. For example, the drug clonidine used for high blood pressure can be confused with the drug clonazepam used for anxiety; Celebrex for arthritis can be confused with Celexa for depression. To help health care professionals differentiate between look-alike and sound-alike drugs, **Tall Man Lettering** is often used to highlight the differences between the two drugs. For example, Celexa would be written CeleXA, whereas Celebrex would be written CeleBREX. This ensures that the health care professional reads and recognizes the correct medication.

These two agencies have created a long-standing relationship with a goal of preventing drug errors. The ISMP has developed tools such as the "List of Confused Drug Names" as a quick drug reference that is available on its website at http://www.ismp.org.

Always keep a drug reference handy, and use it when you are unfamiliar with the generic components of a drug ordered for a patient with known drug allergies. With experience, you will learn and remember the names of products most commonly used at your facility.

LEGAL TERMS REFERRING TO DRUGS

A drug may be referred to by terms other than its classification, generic name, trade name, chemical name, or official name. As mentioned in Chapter 1, the following terms imply the legal accessibility of a drug:

1. ***Over-the-counter (OTC) drug***. No purchasing restrictions by the FDA (with some exceptions, such as pseudoephedrine, which is OTC, but kept behind the pharmacy counter; see Chapter 20)
2. ***Legend drug***. Prescription drug; determined unsafe for OTC purchase because of possible harmful side effects if taken indiscriminately; includes birth control pills, antibiotics, cardiac drugs, and hormones
3. ***Controlled substance***. Drug controlled by prescription requirement because of the danger of addiction or abuse; indicated in references by schedule numbers C-I to C-V (see Chapter 1)

In time and with patient research, some prescription drugs can be deemed safe enough to be sold OTC. The OTC Drugs Advisory Committee was formed in 1992 to review prescription or legend drugs and assist the FDA in determining which ones are safe for OTC designation. Some recent examples of previously prescribed medications now available OTC are fexofenadine (Allegra) and triamcinolone (Nasacort) approved for nasal allergies in 2011 and 2014, respectively.

The legend drug is so named because it requires a legend or warning statement that says, "Federal law prohibits dispensing without a prescription."

Used with permission from Endo Pharmaceuticals, Inc.

FIGURE 2-1 Information contained on a drug label including the trade name (Percocet) and the generic names of the two drugs (oxycodone and acetaminophen) that it contains.

Figure 2-1 shows the information contained on a drug label including the trade name (Percocet) and the generic names of the two drugs (oxycodone and acetaminophen) that it contains. In addition, can you find the controlled substance marking?

TERMS INDICATING DRUG ACTIONS

Most references follow a similar format in describing drugs. When you research drug information, you will find the following terms as headings under each drug. You will find specific information more quickly if you understand what is listed under each heading.

Indications. A list of medical conditions or diseases for which the drug is meant to be used (e.g., diphenhydramine hydrochloride [Benadryl] is a commonly used drug; indications include allergic rhinitis, mild allergic skin reactions, motion sickness, and mild cases of parkinsonism).

Actions. A description of the cellular changes that occur as a result of the drug. This information tends to be very technical, describing cellular and tissue changes. Although it is helpful to know what body system is affected by the drug, this information is geared more for the pharmacist (e.g., as an antihistamine, Benadryl appears to compete with histamine for cell receptor sites on effector cells).

Contraindications. A list of conditions for which the drug should *not* be given (e.g., two common contraindications for Benadryl are breast-feeding and hypersensitivity).

Cautions. A list of conditions or types of patients that warrant closer observation for specific side effects when given the drug (e.g., due to atropine-like

activity, Benadryl must be used cautiously with patients who have a history of bronchial asthma or glaucoma, or with older adults [see Chapter 27]).

Side effects *and* ***adverse reactions***. A list of possible unpleasant or dangerous secondary effects, other than the desired effect (e.g., side effects of Benadryl include sedation, dizziness, disturbed coordination, epigastric distress, anorexia, and thickening of bronchial secretions). This listing may be quite extensive, with as many as 50 or more side effects for one drug. Because it is difficult to know which are most likely to occur, choose a reference that highlights the most common side effects. Certain drugs may have side effects with which you are not familiar. Note the definitions of the following three side effects associated with specific antibiotics.

- Ototoxicity causes damage to the eighth cranial nerve, resulting in impaired hearing or ringing in the ears (tinnitus). Damage may be reversible or permanent.
- Nephrotoxicity causes damage to the kidneys, resulting in impaired kidney function, decreased urinary output, and renal failure.
- Photosensitivity is an increased reaction to sunlight, with the danger of intense sunburn.

Interactions. A list of other drugs or foods that may alter the effect of the drug and usually should not be given during the same course of therapy (e.g., monoamine oxidase [MAO] inhibitors will intensify the effects of Benadryl; you will find MAO inhibitors listed under interactions for many drugs; the term refers to a group of drugs that have been used for the treatment of depression; it has been found that they can cause serious blood pressure changes, and even death, when taken with many other drugs and some foods).

Other headings often listed under information about a drug include "How Supplied" and "Usual Dosage." "How Supplied" lists the available forms and strengths of the drug. "Usual Dosage" lists the amount of drug considered safe for administration, the route, and the frequency of administration. For example:

How supplied: tablets (tabs): 20 mg and 40 mg; suppository: 20 mg
Usual dosage: 10 mg orally every four hours (q4h)

For a listing of common abbreviations regarding drug administration and medication orders, see Tables 4-1 and 5-1 in the upcoming chapters.

DRUG REFERENCES

Physicians'Desk Reference (PDR) is one of the most widely used references for drugs in current use. It is available online, as a mobile app, and in book form. There are three versions of the *PDR*, one for physicians, one for nurses, and one for consumers. In addition, there are many new choices of references available today. Three are compared here, including the *PDR*. You must find the reference most suitable for you, one that you can interpret quickly and easily. By becoming knowledgeable about the drugs you administer, you may prevent possible drug errors from occurring.

Physician's Desk Reference (PDR)*

PROS	CONS
1. *PDR* for physicians—available for free online, as a mobile app, and for a fee in book form. Benefits include the following: —Product labeling —FDA drug safety communication —Medication guide —Drug alerts, recalls, and approvals —Patient resources —Various tools such as e-Books and mobile *PDR* —Ability to report of adverse reactions —Photographs of many drugs for product identification 2. *PDR* for nurses—available for a fee free mobile apps —Includes 1,500 FDA-regulated drugs —Includes critical black box warnings 3. *PDR* for consumers—written in patient-friendly language —Includes over 300 prescribed drugs —Color images of medications —Comparison tables of OTC drugs —Guide to safe medication use	Contains only those drugs that manufacturers pay to have incorporated Incomplete with regard to OTC drugs, making it necessary to buy *PDR* OTC book

*Published annually by PDR Network, LLC, Montvale, New Jersey.

United States Pharmacopeia and the National Formulary (USP/NF)†

PROS	CONS
Information is available online at http://www.usp.org Provides information on and standards for chemical and biological drug substances, dosage forms, and compounded preparations; medical devices; and dietary supplements	No photographs of drugs Geared for laboratory and manufacturing use No easily identified nursing implications Can be confusing to use

†Published annually by U.S. Pharmacopeial Convention, Inc., Rockville, Maryland.

AHFS Drug Information (American Health-System Formulary Service)‡

PROS	CONS
Distributed to practicing physicians; single paperback volume, includes mobile drug reference and handbook to injectable drugs Good, concise information; easy to read Arranged by classifications, with a general statement about each classification at the beginning of each section Off-label drug indications are listed (not FDA approved) http://www.ashp.org/	Some parts (e.g., "Chemical Information" and "Drug Stability") not necessary for the health care professional No photographs of drugs

‡Published annually by American Society of Health-System Pharmacists, Bethesda, Maryland.

Other references (e.g., *The Pill Book, Handbook of Nonprescription Drugs*) may be found in bookstores, but they may not contain adequate information for the health care professionals. Your school may recommend a specific drug reference other than the three listed in this text. Many new references geared to the nurse or health care professional are currently being published. Electronic drug references such as Lexi-Drugs and/or Epocrates (a free version of this) are also widely used.

THE INTERNET AS REFERENCE

The Internet offers a wealth of information regarding medications and the conditions they treat. However, there can be serious dangers associated with some online sources that may not be reliable, professional, or even legitimate. Therefore, care must be taken to identify and use only websites that are supervised and controlled, such as those under the auspices of government agencies or sponsored by professional pharmacist groups. It is important for the health care professional to obtain accurate information and also be able to direct the patient or client to reliable sources of information regarding medicines. It is the health care professional's responsibility to caution the layperson regarding the controversial and dangerous practices of "online prescribing" without ever evaluating the patient in person, or obtaining medicines without prescriptions through the Internet.

EVALUATING INTERNET DRUG SOURCES

Remember that all websites are not created equal. Pay attention to a few simple rules when seeking the most reputable ones.

1. Check the source. Have scientific studies been done with a large enough sample? Are results reliable and valid? Are there links to a page listing professional credentials or affiliations?
2. Check the date of articles. Medicine is a rapidly evolving field. Information can go out of date quickly.
3. Be wary of information from forums and testimonials. Motivations are unknown. The information is not necessarily valid, and there may be a hidden agenda.

The following websites are reliable professional sources of medical information:

http://www.pharmacist.com	Sponsored by the American Pharmacists Association (APhA), the national professional society of pharmacists.
http://www.fda.gov	U.S. Food and Drug Administration. Includes "Human Drugs" and Center for Drug Evaluation and Research (CDER).
http://www.safemedication.com	Sponsored by the American Society of Health-System Pharmacists. Covers correct dosage, side effects, and optimal use of most prescriptions and OTC drugs. Also offers reports on topics such as antibiotic-resistant bacteria.
http://www.usp.org	U.S. Pharmacopeial Convention (USP/DI). (See United States Pharmacopeia, previous page.)
http://www.cdc.gov/vaccines/	U.S. Centers for Disease Control and Prevention, National Immunization Program. Covers vaccines and immunizations.
http://www.nlm.nih.gov/medlineplus/	A service of the U.S. National Library of Medicine and the National Institutes of Health. A great source for medicine and related health topics.

CHAPTER REVIEW QUIZ

Match the definition with the term.

1. ___ List of conditions for which a drug is meant to be used

2. ___ Subcategories of drugs based on their effects on the body

3. ___ Description of the cellular changes that occur as a result of a drug

4. ___ Conditions for which a drug should not be given

a. Contraindications

b. Precautions

c. Indications

d. Prototype

e. Actions

f. Classifications

Refer to the following drug description to answer questions 5–8.

AZO Standard®
(phenazopyridine HCl tablets, *USP*)
Product of i-Health, a Division of DSM
Description: AZO Standard (phenazopyridine HCl) is a urinary tract analgesic agent, chemically designated 2,6-pyridinediamine, 3-(phenylazo), monohydrochloride.

5. The generic name of the drug is _____.

6. The chemical name of the drug is _____.

7. The trade name of the drug is _____.

8. What is indicated by the ® symbol after the drug name?

_____.

9. Explain when Tall Man Lettering should be used:

_____.

10. Explain the difference between these two medication orders:
a. Give two Tylenol, PO.
b. Give one Tylenol No 2 PO.

_____.

_____.

11. An older adult male was found unconscious in his bedroom with several pink and blue pills beside his bed, but no labeled pill bottle can be found. He is rushed to the emergency department for treatment. What drug reference source will be most helpful in this situation?

_____.

STUDYGUIDE
PRACTICE

Complete Chapter 2

Online Resources

- Powerpoint presentations
- Videos

CHAPTER 3

SOURCES AND BODILY EFFECTS OF DRUGS

KEY TERMS AND CONCEPTS

Adverse drug reaction
Anaphylactic reaction
Chemoinformatics
Cumulative effect
Dependence
Dosage
Drug interactions
Drug processes
Hypersensitivity
Idiosyncratic reaction
Keep Vein Open (KVO)
Local effect
Paradoxical reaction
Pharmacogenomics
Placebo effect
Prodrugs
Sources of drugs
Systemic effect
Teratogenic effect
Therapeutic range
Tolerance

OBJECTIVES

Upon completion of this chapter, the learner should be able to

1. Identify the five sources of drugs
2. Differentiate among the following: drug actions and drug effects, systemic effects and local effects, loading dose and maintenance dose, and toxic dose and lethal dose
3. Define the following processes as they relate to the passage of drugs through the body and state conditions that may decrease the effectiveness of each: absorption, distribution, metabolism, and excretion
4. Define the following terms: selective distribution, toxicity, placebo, synergism, potentiation, and antagonism
5. List several variables that may affect the action of drugs
6. Identify and contrast the various routes of drug administration
7. Define adverse drug reactions
8. Define the Key Terms and Concepts

SOURCES OF DRUGS

Any chemical substance ingested or applied on the body for the purpose of affecting body function is referred to as a drug. In earlier times, these substances were found in nature, sometimes accidentally. Plants were the primary **sources of drugs** used on the human body. Berries, bark, leaves, resin from trees, and roots were found to aid the body and are still very important drug sources.

Minerals from the earth also found their way into human use as drugs. Minerals such as iron, sulfur, potassium, silver, and even gold are used to manufacture drugs.

More sophisticated sources of drugs emerged as human beings progressed. Research led to the use of substances from *animals* as effective drugs. Substances lacking in the human body can be replaced with similar substances obtained from the glands, organs, and tissues of animals. Investigation of other animal sources of medicines still remains. For example, an investigational drug to treat Type 2 diabetes by promoting weight loss was recently developed from the saliva of the Gila monster lizard.

Chemists use synthetic sources to make drugs to market for human consumption. The *synthetic* (manufactured) sources evolved with human skills in laboratories and advanced understanding of chemistry. Today, through advances in computers, millions of potential drug candidates can be screened on computers quickly and efficiently using a process called **chemoinformatics**. Chemoinformatics is the application of computer technology, statistics, and mathematics to study information about the structure, properties, and activities of molecules. This method is probably the most actively pursued source of drugs by major companies today. Competitive research is a big industry that involves experimenting with chemicals to discover cures for current medical problems. Numerous antibiotics are synthetic or semisynthetic, the results of researchers meeting the need for better treatment of infections. Someday the cure for cancer or human immunodeficiency virus (HIV) infection may be found from a synthetic source developed in a laboratory.

Genetic engineering of drugs and the recently developed technique of *recombinant DNA technology* has allowed for the production of biologically active substances that are present in the body and that can be used to treat certain diseases. DNA is the genetic material of the cells, and the DNA sequence determines the genetic code. Genetic engineering refers to the alteration of genes in a laboratory setting.

Recombinant DNA techniques involve combining the DNA of two or more different organisms for a desired change or improvement. Some examples of therapeutic agents derived by recombinant DNA technology are hepatitis B vaccine, insulin, and growth hormone. One of the areas of most current interest in recombinant DNA technology is gene therapy. This therapy consists of essentially inserting normal genes into a human chromosome to counteract the effects of an abnormal or a missing gene. This not only has huge implications for preventive medical therapy but also ethical considerations. See Figure 3-1 for examples of sources of drugs.

EFFECTS OF DRUGS

Regardless of the source, the common characteristic of all drugs is the ability to affect body function in some manner. When introduced into the body, all drugs cause cellular changes (drug actions), followed by some *physiological change* (effects of drugs). Generally, drug effects may be categorized as systemic or local:

1. **Systemic effect**. Reaches widespread areas of the body. For example, ibuprofen is often used as an analgesic and anti-inflammatory for pain associated with knee pain due to arthritis. Although you feel the effect in

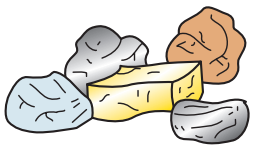
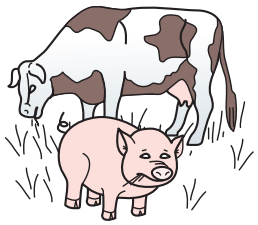
Sources of Drugs	Example	Trade Name	Classification
 Plants	Cinchona Bark	Quinidine	Antiarrhthymic
	Purple Foxglove Plant	Digitalis	Cardiotonic
	Poppy Plant (Opium)	Morphine, Codeine	Analgesic Analgesic, Antitussive
 Minerals	Magnesium	Milk of Magnesia	Antacid, Laxative
	Zinc	Zinc Oxide Ointment	Sunscreen, Skin Protectant
	Gold	Auranofin	Anti-inflammatory; Used in the Treatment of Rheumatoid Arthritis
 Animals	Thyroid Gland of Animals	Thyroid, USP	Hormone
 Synthetic	Meperidine	Demerol	Analgesic
	Diphenoxylate	Lomotil	Antidiarrheal
	Co-Trimoxazole	Bactrim, Septra	Anti-infective Sulfonamide; Used in the Treatment of Urinary Tract Infections (UTI) and Some Other Infections
DNA  Genetic Engineered	Hepatitis B vaccine	Recombivax HB	Vaccine
	Insulin	Humulin, Novolin	Anti-diabetic
	Growth hormone	Nutropin	Hormone

FIGURE 3-1 Sources of drugs: plants, minerals, animals, synthetic, and genetically engineered.

your knee, the medication is actually providing the same effects all over the body, which is why it can also be used for headaches, cramps, and sunburn just to name a few.

2. **Local effect**. Is limited to the area of the body where it is administered (e.g., dibucaine ointment [Nupercainal], applied rectally, affects only the rectal mucosa to reduce hemorrhoidal pain).

DRUG PROCESSING BY THE BODY (PHARMACOKINETICS)

***Kinetics* means "movement" and therefore *pharmacokinetics* literally means what happens to the drug as it moves through our body.**

Within the body, drugs undergo several changes. From start to finish, the biological changes consist of four **drug processes** (abbreviated as *ADME*):

1. ***Absorption.*** Passage of a substance through a membrane into the bloodstream
2. ***Distribution.*** Moving from the bloodstream into the tissues and fluids of the body
3. ***Metabolism.*** Physical and chemical alterations that the substance undergoes in the body
4. ***Excretion.*** Eliminating waste products of drug metabolism from the body

Many variables affect how quickly or successfully substances go through the body via these four processes. If any of the four processes are altered, the drug action and effects will be altered, where the medication may have a greater or lesser effect or a longer or shorter duration. Table 3-1 lists conditions that may alter each process.

TABLE 3-1 Processing of Drugs within the Body

PROCESS	PRIMARY SITE OF PROCESS	CONDITIONS THAT MAY ALTER PROCESS
Absorption	Mucosa of the stomach, mouth, small intestine, or rectum; blood vessels in the muscles or subcutaneous tissues; or dermal layers	Incorrect administration may destroy the drug before it reaches the bloodstream or its site of action (e.g., giving certain antibiotics after meals instead of on an empty stomach)
Distribution	Circulatory system, through capillaries and across cell membranes	Poor circulation (impaired flow of blood) may prevent the drug from reaching tissues
Metabolism	Liver, small intestine	Hepatitis, cirrhosis of liver, or a damaged liver may prevent adequate breakdown of the drug, thus causing a build-up of unmetabolized drug
Excretion	Kidneys, sweat glands, lungs, or intestines	Renal damage or kidney failure may prevent passage of drug waste products, thereby causing an accumulation of the drug in the body

FIGURE 3-2 Warning labels are placed on prescription medication containers. Patients should be advised to read and follow the precautions or instructions.

Directions for the administration of drugs may vary widely because the physical properties of the drugs may vary widely. The specific directions ("Usual Dosage and Administration," "Contraindications," and "Warnings") that accompany each drug are given to enhance the absorption, distribution, metabolism, and excretion of the drug. For example, directions to "Give on an empty stomach" ensure the most effective means of absorption. "Use cautiously in patients with renal dysfunction" implies possible effects on the excretion of a drug. "Decrease dose in patients with hepatic dysfunction" implies possible effects on the metabolism of a drug. *Read all labels carefully, and caution the patient to do so as well* (Figure 3-2).

Absorption

The site of absorption of drugs varies according to the following physical properties of each drug:

1. ***pH.*** Drugs of a slightly acidic nature (e.g., aspirin and tetracycline) are absorbed well within the acidic stomach environment. Drugs of an alkaline pH are not absorbed well through the stomach but are readily absorbed in the alkaline environment of the small intestine. The antibiotic tetracycline is not recommended to be administered with milk, dairy products, or antacids, because it will not be properly absorbed. This is due to *chelation*—the formation of an insoluble complex of tetracycline with calcium in dairy products. pH effect may also play a role. It varies with the specific antacid used. Oral medications for infants (syrups and solutions) may not be absorbed well after infant feedings. The milk or formula neutralizes the acidity of the stomach. Thus,