# *Essentials of Pharmacology for Health Professions 9th edition Colbert Solutions Manual*

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# Solution and Answer Guide

Colbert, Essentials of Pharmacology, 9e, © 2023, 9780357618301; Chapter 2: Drug Names and References

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## Chapter Review Quiz Answers

Match the definition with the term.

| Definition | Term Answer |
|---|---|
| 1. List of conditions for which a drug is meant to be used | c. Indications |
| 2. Subcategories of drugs based on their effects on the body | f. Classifications |
| 3. Description of the cellular changes that occur as a result of a drug | e. Actions |
| 4. Conditions for which a drug should not be given | a. Contraindications |

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

_____

**Answer:** phenazopyridine HCl

**Feedback**: The generic name of a drug is a common or general name assigned to the drug by the United States Adopted Name (USAN) council. It is different from the trade name by initial lowercase letter and never capitalized.

6. The chemical name of the drug is

_____

**Answer:** 2,6-pyridinediamine, 3-(phenylazo), monohydrochloride

**Feedback**: The chemical name of a drug describes the exact molecular formula of the drug and usually comprises of long, very difficult name to pronounce.

7. The trade name of the drug is

_____

**Answer:** AZO Standard

**Feedback**: The trade name of a drug is the name by which a pharmaceutical company identifies its product. It is copyrighted and used exclusively by that company and is different from the generic name by capitalized first letter. It is often shown on labels and references with the symbol ® (for "registered" trademark) after the name.

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

   _____

   **Answer:** A symbol associated with copyright or patent and refers to a name used exclusively by the drug company possessing that copyright or patent.

   **Feedback**: The symbol ® means "registered" trademark, which is often associated with the trade name of a drug (also see feedback to question 7 above)

9. Explain when Tall Man Lettering should be used._____

   **Answer:** It is used to highlight the differences between look-alike and sound-alike drug.

   **Feedback**: 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.

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

    **Answer:** Although both medications are to be taken orally, the first order is for two Tylenol (acetaminophen) whereas the second order is a prescription for a controlled substance because it is for a single dose of a combination product consisting of acetaminophen and codeine.

    **Feedback**: Tylenol is not the same as Tylenol in combination with different amount of codeine, and one such example is Tylenol No. 2.

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?

    **Answer:** Any of the following references are correct:

    - AHFS Drug Information (American Health-System Formulary Service)
    - Physicians' Desk Reference (PDR)
    - U.S. Pharmacopeia/Dispensing Information (USP/DI)
    - Reliable professional websites such as

    **http://www.fda.gov**

    **http://www.pharmacist.com**

    **http://www.nlm.nih.gov/medlineplus**

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http://www.safemedication.com

http://www.cdc.gov/vaccines/

http://www.usp.org

**Feedback**: Although there are multiple choices of references available today, some examples of useful drug references as well as creditable websites are indicated above.

12. Place the following terms in the correct blank: OTC, controlled substance, legend drug, off-label
    a. a prescription is not needed

    **Answer:** OTC

    **Feedback**: OTC means over the counter and hence no prescription is required.

    b. term that means a prescription is required

    **Answer**: Legend drug

    **Feedback**: A legend drug is one that is determined unsafe for OTC purchase because of possible harmful side effects if taken indiscriminately. As a result, a prescription from a health care provider is necessary.

    c. potential for abuse

    **Answer**: Controlled substance

    **Feedback**: Controlled substances are abused and addicting drugs with different medical value, harmfulness, and potential for abuse or addiction.

    d. drug given for an unapproved use

    **Answer**: Off-label

    **Feedback**: Drugs approved by the Food and Drug Administration (FDA) have one or more official indications. On the other hands, a drug can be used off-label by some clinicians based on their own experience, and the use of such drugs for use unapproved by the FDA is known as off-label use.

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# Solution and Answer Guide

Colbert, Essentials of Pharmacology, 9e, © 2023, 9780357618301; Chapter 1: Consumer Safety and Drug Regulations

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## Chapter Review Quiz Answers

1. The first major U.S. drug law was passed in the year _____ and was called the _____

   **Answer**: 1906, Pure Food and Drug Act

   **Feedback**: The Pure Food and Drug Act is the first drug law passed in 1906 to ensure consumer safety.

2. USP stands for _____

   **Answer**: United States Pharmacopeia

   **Feedback**: The United States Pharmacopeia is a reference that specifies the official U.S. standards for making individual drugs.

3. NF stands for _____

   **Answer**: National Formulary

   **Feedback**: The National Formulary (NF) is another reference that specifies the official U.S. standards for making individual drugs. It has been combined with the United States Pharmacopeia (USP) into one reference book, the USP/NF

4. Which drug law established the USP and NF (which are now one)?

   **Answer**: The Pure Food and Drug Act

   **Feedback**: The 1906 Pure Food and Drug Act established two references of officially approved drugs: the USP and NP, which were subsequently combined into one single reference source.

5. The agency that requires you to keep a record of each controlled substance transaction is the _____

   **Answer**: Drug Enforcement Agency

   **Feedback**: The Drug Enforcement Administration enforces security and accountability related to controlled substances. Anyone 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.

6. Schedule C-_____ has the lowest potential for abuse.

   **Answer**: Schedule C-V has the lowest potential for abuse

   **Feedback**: The 1970 Controlled Substances Act classified abused and addicting drugs into five levels, or schedules, according to their medical value, harmfulness,

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and potential for abuse or addiction: C-I, C-II, C-III, C-IV, and C-V, with class C-1 being the highest potential for abuse, and C-V with the lowest potential for abuse.

7. How long must you keep an inventory record of each controlled substance transaction at your office? ___

   **Answer**: Two years

   **Feedback**: The Drug Enforcement Administration enforces security and accountability related to controlled substances, including a two-year inventory of every controlled substance transaction (also see feedback to question 5).

8. Three responsibilities of the FDA include:
   _____

   **Answer**: Three responsibilities of the FDA may include <u>any of the following</u>:

   - Oversee testing of all proposed new drugs before they are approved for marketing
   - Investigate and remove unsafe drugs from the market
   - Ensure proper labeling of drugs, foods, and cosmetics
   - Review new drug applications and petitions for food additives
   - Inspect plants where foods, drugs, medical devices, or cosmetics are made

   **Feedback**: 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 the five listed in the answers above.

9. What types of drugs are listed in the C-V schedule?
   _____

   **Answer**: Drugs that have the lowest abuse potential among the five classes or schedules of controlled substance, and primarily consist of cough suppressants containing codeine and antidiarrheal preparations such as diphenoxylate

   **Feedback**: The 1970 Controlled Substances Act classified 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, and drugs with the C-V classification have the lowest potential for abuse.

10. What method is recommended for securing the controlled substances at your office? _____.

    **Answer**: The drugs should be kept inside a locked safety box, which is then placed within in a cupboard that is also locked.

    **Feedback**: The Drug Enforcement Administration enforces security and accountability related to controlled substances, including that all controlled

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substances must be kept inside a locked safety box, which is then placed within in a cupboard that is also locked.

11. If a patient calls to request a refill of a Percocet (C-II) prescription, how would you reply? _____

    **Answer**: A refill for a C-II substance cannot be called into a pharmacy as a new prescription is required by law.

    **Feedback**: The 1970 Controlled Substances Act set regulations as to which schedules prescriptions may be phoned in to the pharmacy. A refill for a C-II substance cannot be called into a pharmacy as a new prescription is required.

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?

    **Answer**: The Orphan Drug Act of 1983

    **Feedback**: The 1983 Orphan Drug Act provides pharmaceutical companies financial incentives to develop medications for diseases that affect only a small number of people, so that orphan drugs that would otherwise be of low profitability would be available to patients with rare diseases.

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?

    **Answer**: The medication taking behavior suggests a potential pattern of drug abuse. Nevertheless, the most appropriate action should be to notify the patient's physician so that s(he) can assess the real need of an increase in the dose and/or frequency of administration.

    **Feedback**: The prescription fill record indicated that the patient is getting the narcotic more frequently that what is allowed by his physician for his medical condition. Given the high potential of narcotic abuse, such request needs to be addressed by the physician.

14. Each drug is given a _____ number to identify the manufacturer, the drug, and the package size.
    a. FDA
    b. USP
    c. DEA
    d. NDC

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**Answer: d**

**Feedback**: The National Drug Code (NDC) is a directory of numerical code that allows identification of a drug, as well as the package size and the manufacturer. This directory provides a list of all drugs manufactured for commercial distribution. The NDC is comprised of three parts: the first part is five numbers and identifies the manufacturer., the second part is four numbers and identifies the drug, and the third part is two digits that identifies the package size.

15. Drug standards insure consistency in all the areas EXCEPT
    a. strength
    b. purity
    c. quality
    d. size

**Answer: d**

**Feedback**: Drug standards assure consumers that the drug they take are of uniform strength, purity, and quality

16. The Federal Food, Drug, and Cosmetic Act of 1938 established which agency?
    a. NDC
    b. DEA
    c. FDA
    d. USP

**Answer: c**

**Feedback**: The Federal Food, Drug, and Cosmetic Act of 1938 established the Food and Drug Administration (FDA).

17. The earliest recorded use of drugs occurred during which civilization?
    a. Egyptian
    b. Roman
    c. Greek
    d. Aztec

**Answer: a**

**Feedback**: The first documented use of drug was in ancient Egypt.

18. Answer the questions concerning the following three drug labels:
    a. Which drug(s) requires a prescription?

**Answer**: Morphine Sulfate and Procardia (nifedipine)

**Feedback**: Both Morphine and Procardia (nifedipine) require a prescription and cannot be purchased over the counter.

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b. Which drug(s) can be bought without a prescription?

**Answer**: Acetaminophen

**Feedback**: Acetaminophen can be obtained over the counter from any pharmacy without a prescription.

c. Which drug(s) requires a DEA number?

**Answer**: Morphine Sulfate

**Feedback**: Morphine is a controlled substance that requires not only a prescription but also that the ordering and dispensing, respectively, needs to be by a physician and a pharmacist that have a DEA number indicating their proper registration with the agency.

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# Worksheets for Textbook Part II

## Worksheet 1 for Chapter 11

## Fat-Soluble Vitamins (see Table 11-1)

| Vitamins | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| A | Animal<br>Oily saltwater fish<br>Dairy products<br>Eggs<br>Plants<br>Dark-green leafy vegetables<br>Deep yellow or orange fruit and vegetables | Malabsorption of fats or diarrhea<br>Obstruction of bile<br>Presence of mineral oil in the intestines<br>Overcooking of vegetables in an open container (heat and air cause oxidation)<br>Prolonged infection or fever | Retarded growth<br>Faulty bone and tooth development<br>Night blindness<br>Dry skin<br>Xerophthalmia (dry eyes) | Irritability, lethargy, headache<br>Joint pain, myalgia<br>Stunted growth, fetal malformations<br>Jaundice, nausea, diarrhea<br>Dry skin and hair | *Cautions:*<br>Caution should be used in patients with kidney or liver problems or diabetes<br>*Interactions:*<br>Long-term use of large doses of vitamin A is contraindicated for women who are, or may become, pregnant. Fetal malformations have been reported following maternal ingestion of large doses of vitamin A, either before or during pregnancy |

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| Vitamins | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| D | Animal<br>Fish oils<br>Fortified milk<br>Plants<br>Fortified cereals | | Softening bones:<br>Rickets (in children)<br>Osteomalacia (in adults)<br>Poorly developed teeth<br>Muscle spasms | Convulsions<br>Kidney stones, kidney damage<br>Muscle/bone pain<br>Nausea, anorexia<br>Fetal disorders | *Cautions:*<br>Not to exceed the RDA of vitamin D especially in patients with cardiovascular diseases, kidney diseases, pregnancy, breast feeding<br>*Interactions:*<br>Digitalis, thiazide diuretics; mineral oil may interfere with intestinal absorption of vitamin D |
| E | Plants<br>Vegetable oils<br>Seeds, nuts<br>Wheat germ, cereals | Alcohol abuse<br>Malabsorption syndromes<br>Pathologic conditions of liver and pancreas<br>Premature infants or low-birth-weight neonates | Destruction of RBCs, muscle weakness | Prolonged bleeding time | *Interactions:*<br>Vitamin E supplements should be taken at the lowest dosage necessary while on anticoagulant therapy because of increased risk of bleeding<br>Excessive use of mineral oil may decrease absorption |

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| Vitamins | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| K | Animal<br>Egg yolk, cheese<br>Liver<br>Plants<br>Vegetable oil<br>Green leafy vegetables<br>Cabbage, broccoli | Reduced prothrombin in the blood due to insufficient clotting factors in the newborn<br>Malabsorption syndromes<br>Coumarin overdose<br>Prolonged use of salicylates, quinine, long-term parenteral nutrition, or broad-spectrum antibiotics | Prolonged blood clotting time<br>Blood in urine and stool | Jaundice in infants | *Cautions:*<br>Patients receiving anticoagulant therapy should be consistent in the amount of vitamin K–rich foods they eat daily in order to keep prothrombin and other vitamin K–dependent clotting factor levels stable |

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# Worksheet 2 for Chapter 11

## Water-Soluble Vitamins (see Table 11-1)

| Vitamin | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| $B_1$ (thiamine) | Animal<br>Pork, beef, liver<br>Oysters<br>Plants<br>Yeast<br>Whole and enriched grains, wheat germ<br>Beans, peas, collard greens, nuts, asparagus<br>Oranges | Chronic alcoholism<br>Malabsorption | GI upset, constipation<br>Neuritis, mental disturbance<br>Cardiovascular problems<br>Muscle weakness, fatigue | None known | |
| $B_2$ (riboflavin) | Animal<br>Milk<br>Meat, liver<br>Plants<br>Green vegetables<br>Cereals<br>Enriched bread<br>Yeast | Chronic alcoholism<br>Poor diet | Glossitis<br>Cheilosis<br>Dermatitis<br>Photophobia<br>Vision problems, itching eyes, rough skin | None | |

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| Vitamin | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| $B_6$ (pyridoxine) | Animal<br>Pork, beef, chicken, tuna, salmon<br>Plants<br>Whole-grain cereals, wheat germ<br>Legumes, peanuts, soybeans<br>Bananas | Chronic alcoholism<br>Cirrhosis<br>Malabsorption syndromes | Anorexia, nausea, vomiting<br>Dermatitis<br>Neuritis, depression | Seizures in newborns | *Cautions:*<br>Overdose in pregnant women may result in newborns with seizures who have developed a need for greater-than-normal amounts of pyridoxine |
| $B_{12}$ (cobalamin, cyanocobalamin) | Animal<br>Seafood/shellfish<br>Meat, poultry, liver<br>Eggs<br>Milk, cheese<br>Plants | Vegetarian diets without meats, eggs, or milk products<br>Gastrectomy or intestinal resections<br>Malabsorption syndromes<br>Pernicious anemia | Nerve, muscle, and mental problems<br>Pernicious anemia | None | *Interactions:*<br>*Neomycin*<br>Colchicine |

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| Vitamin | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| $B_9$ (folic acid) | Animal<br>Organ meats<br>Plants<br>Green leafy vegetables<br>Avocado, beets<br>Broccoli, kidney beans<br>Orange juice | Improper diet<br>Chronic alcoholism<br>Liver pathology<br>Intestinal obstruction<br>Malabsorption syndromes<br>Malnutrition<br>Renal dialysis or prolonged use of some medications | Increased risk of neural tube defects<br>Macrocytic anemia<br>Irritability, behavior disorders | None | *Cautions:*<br>Never give to someone with undiagnosed anemia<br>*Interactions:*<br>Phenytoin, barbiturates |
| $B_3$ (niacin) | Animal<br>Milk<br>Eggs<br>Fish<br>Poultry<br>Plants<br>Legumes, nuts<br>Green vegetables | | Pellagra | Headache, flushing<br>Increased blood glucose and uric acid | *Cautions:*<br>Patients with liver disease, gallbladder disease, gout, diabetes |

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# Worksheet 3 for Chapter 11

## Water-Soluble Vitamins and Minerals (see Tables 11-1, & 11-3)

| Vitamin/Mineral | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| C (ascorbic acid) | Fruits<br>All citrus, cantaloupe<br>Plants<br>Broccoli<br>Tomatoes<br>Brussels sprouts<br>Cabbage<br>Green peppers | Diet lacking fresh fruit and vegetables<br>Alcoholism<br>Infections<br>Smoking | Scurvy<br>Poor healing<br>Muscle cramps/weakness<br>Ulcerated gums/mouth, loose teeth<br>Capillary fragility (bruising) | Raised uric acid level, gout<br>GI distress<br>Kidney stones<br>Rebound scurvy in neonates | *Interactions:*<br>Aspirin, barbiturates, tetracyclines, estrogens, oral contraceptives, alcohol, and smoking |

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| Vitamin/Mineral | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| Potassium (K) | Oranges, bananas<br>Dried fruits<br>Tomatoes | Insufficient oral intake due to surgery, anorexia, or weight-reduction diets<br>Diarrhea or vomiting<br>Diabetic ketoacidosis<br>Diaphoresis (excessive perspiration)<br>Diuretic use, especially thiazides and furosemide loop diuretics<br>Digoxin toxicity<br>Long-term use of corticosteroids or long-term use of laxatives<br>Kidney disease | Muscular weakness<br>Cardiac arrhythmias<br>Lethargy<br>Mental apathy and confusion | Confusion<br>Weakness<br>Cardiac arrhythmias | *Cautions:*<br>Cardiac disease, renal impairment, gastric or intestinal ulcers, mental confusion |

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| Vitamin/Mineral | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| Calcium (Ca) | Milk, cheese, yogurt<br>Sardines<br>Salmon<br>Green vegetables except spinach | Pregnancy and breast feeding<br>Hypoparathyroidism<br>Long-term use of corticosteroids, some diuretics, or anticonvulsants<br>Chronic diarrhea<br>Pancreatitis<br>Renal failure<br>Lack of weight-bearing exercise | Osteoporosis<br>Osteomalacia<br>Rickets in children<br>Cardiac myopathy<br>Tetany and leg cramps | Constipation<br>Cardiac arrhythmias if IV calcium not injected slowly | *Cautions:*<br>Cardiac disease, renal disease, respiratory conditions<br>*Interactions:*<br>Digitalis (resulting in potentiation), tetracycline (resulting in antagonism) |
| Iron (Fe) | Meat<br>Liver<br>Eggs<br>Poultry<br>Spinach<br>Dried fruits<br>Dried beans<br>Prune juice | Hemorrhage and excessive menstrual flow<br>Internal bleeding, ulcers, and GI tumors<br>Pregnancy<br>Infancy<br>Puberty at time of growth spurt<br>Hemodialysi | Paleness of the skin and/or mucous membranes<br>Lethargy and weakness<br>Vertigo<br>Air hunger<br>Decline in mental skills<br>Irregular heartbeat and cardiac function<br>Cravings for | Shock<br>Vomiting<br>Diarrhea or constipation<br>Black stools | *Interactions:*<br>Vitamin C or orange juice taken at the same time enhances iron absorption<br>Coffee or tea within 2 h of iron reduces iron absorption by as much as 50%<br>Tetracycline |

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| Vitamin/Mineral | Sources | Causes of Deficiencies | Signs of Deficiencies | Symptoms of Overdose | Interactions and Cautions |
|---|---|---|---|---|---|
| | | s | nonfood items, such as ice, clay, or starch | | absorption is inhibited by oral iron preparations when taken within 2 h<br>Antacids decrease iron absorption (should not be given at same time) |

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# Worksheet 1 for Chapter 12

## Drugs for the Skin

| Classifications and Drugs | Purpose | Side Effects | Contraindications or Cautions | Patient Education |
|---|---|---|---|---|
| Antipruritics<br>*Local anesthetics*<br>1. Benzocaine (Lanacane, Americaine, Orajel)<br>2. Dibucaine (Nupercainal)<br>*Antihistamines*<br>1. Diphenhydramine (Benadryl)<br>*Corticosteroids*<br>1. Various (Diprolene, Temovate) | Relieve itching from allergic reactions, poison ivy, hives, and insect bites | Skin irritation<br>Rash<br>Stinging and a burning sensation<br>Allergic reactions (-caines)<br>Sedation from antihistamines | Open wounds or prolonged use (for corticosteroids)<br>Hypersensitivity (severe allergic) reaction to the active drug or any component of the formulation | Clean area before application<br>Rub gently until medication vanishes<br>Use caution if patient has allergies<br>Avoid contact with eyes or mucous membranes<br>Avoid covering with dressings unless ordered by a health care provider<br>Avoid prolonged use (not longer than one week)<br>Discontinue if condition worsens or irritation develops<br>Trim children's fingernails to reduce possibility of infection from scratching |

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| Emollients and Protectants<br>1. Ammonium lactate (AmLactin, Lac-Hydrin)<br>2. Vitamins A and D (A & D, Desitin—with zinc oxide)<br>3. Zinc oxide (Balmex) | Soothe, soften, protect (via creation of a lipid barrier), and seal out wetness in minor dermatological conditions, such as diaper rash, irritation, abrasions, and minor burns | | | |
| Keratolytics<br>1. Coal tar (Balnetar, Polytar, Neutrogena T/Gel)<br>2. Salicylic acid<br>3. Sulfur (Clearasil, Salex, Fostex, Compound W) | Control conditions of abnormal scaling of the skin, such as dandruff, seborrhea, and psoriasis<br>Promote peeling of the skin in conditions such as acne, hard corns, calluses, and warts | Severe skin irritation, pruritis, or stinging<br>Irritation of eyes or mucous membranes<br>Photosensitivity<br>Systemic effects in allergic individuals or with multiple applications and prolonged use (e.g., headache and GI symptoms) | Open areas of skin<br>Hypersensitivity (severe allergic) reaction to the active drug or any component of the formulation | Use only as directed, for entire treatment period, even if improved<br>Avoid contact with eyes and mucous membranes<br>Avoid prolonged use<br>Discontinue and seek medical aid if irritation occurs<br>Avoid contact with surrounding tissues when applied as a caustic to corns or calluses |
| Enzyme Preparations | Remove dead or damaged | | For use on necrotic skin | If a topical antibiotic is to |

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| 1. Collagenase (Santyl) | tissue | | tissue only | be applied to an infected site, the antibiotic is applied before collagenase<br>Avoid using detergents, povidone-iodine, and heavy metal (e.g., mercury, silver) containing agents that will inhibit the enzymatic activity of collagenase |
| Scabicides and Pediculicides<br>1. Permethrin (Elimite, Nix, RID)<br>2. Lindane (Kwell)<br>3. Pyrethrins (RID)<br>4. Ivermectin (Stomectol, Sklice) | Treatment of scabies or lice | Slight local irritation, rash, or conjunctivitis<br>Dermatitis with frequent application | Acutely inflamed, raw, or weeping surfaces<br>Lindane should be avoided during pregnancy, during breast feeding, and with infants, small children, and older adults and those who weigh less than 110 lb or those with known uncontrolled seizure disorders | Follow directions carefully<br>Thoroughly launder (130°F) clothing and bedding and dry using the hot cycle of a dryer for at least 20 min<br>Large items (e.g., pillows, comforters) may be bagged in plastic for two weeks<br>Use caution to prevent accidental oral ingestion |

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| | | | | Use caution with infants who might suck thumbs<br>Inform sexual partner if condition is present in pubic area<br>Alert school to head lice infestation |
| Antifungals<br>1. Clotrimazole (Mycelex, Lotrimin, Gyne-Lotrimin)<br>2. Ketoconazole (Nizoral, Nizoral A-D)<br>3. Miconazole (Monistat, Lotrimin AF)<br>4. Nystatin (Mycostatin)<br>5. Terbinafine (Lamisil AT, Lamisil)<br>6. Tolnaftate (Tinactin) | Treatment of monilial infections such as thrush, diaper rash, vaginitis, athlete's foot, body ringworm, jock itch | Contact dermatitis<br>Itching, burning, and irritation | Vaginal preparations should not be used during pregnancy except under medical supervision | Carefully wash and dry affected areas<br>Expose to air whenever possible<br>With genital fungus, avoid tight undergarments, pantyhose, and wet bathing suits<br>With athlete's foot, use open sandals instead of sneakers<br>*Follow application instructions carefully*. Use for entire time, even if asymptomatic<br>Remove any stains with soap and warm |

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| | | | | water<br>Continue prescribed vaginal treatment even during menstruation, or if symptomatic relief occurs, until entire regimen is completed<br>Consult a health care provider before vaginal preparations are used during pregnancy<br>For oral suspensions or lozenges, apply after meals and after thorough rinsing of mouth. No food or liquids for at least 1 h after treatment<br>For vaginal infections, refrain from intercourse until treatment is complete<br>Consider treating partner if reinfection occurs |

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|---|---|---|---|---|
| Antivirals<br>1. Acyclovir (Zovirax)<br>2. Docosanol (Abreva) | Decrease duration of viral shedding, duration of pain and itching and the time required for crusting and healing of lesions | | | |
| Antibacterials<br>1. Mupirocin (Bactroban) | Treat impetigo caused by *Staphylococcus aureus* and certain species of Streptococci<br>Treat secondarily infected traumatic skin lesions<br>Reduce the risk of infection in patients with high risk during institutional outbreaks of MRSA | Local, hypersensitivity and systemic reactions | | Read and follow carefully all directions on the package<br>Check all ingredients carefully for possible allergies<br>If there is no improvement, the condition worsens, or there are other untoward reactions (e.g., inflammation, itching, rash, or swelling), stop the medication and consult a health care provider |
| Antiseptics<br>1. Chlorhexidine (Hibiclens, Peridex) | Inhibit the growth of bacteria | *Chlorhexidine:*<br>Dermatitis and irritation<br>Photosensitivit | *Chlorhexidine:*<br>Pregnancy<br>Not for frequent use for total body | Rinse chlorhexidine *thoroughly*<br>Avoid use of chlorhexidine |

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# Instructor Manual

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## Purpose and Perspective of the Chapter

The purpose of this chapter is to explain how drug regulations and standards have evolved for the safety of consumers.

## What's New in This Chapter

The following elements are improvements in this chapter from the previous edition:

- Updated Controlled Substances Schedule.
- Added new Section on Drug History along with a Pharmacology Timeline and table
- Added new questions on drug history material
- Added to facts and fallacies table.

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- Educator's Guide (provides an overview of MindTap assets)

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## Chapter Objectives

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

1. Explain what is meant by drug standards.
2. Discuss the historical development of pharmacology.
3. Name the first drug law passed in the United States for consumer safety and give the year it was passed.
4. Summarize the provisions of the Federal Food, Drug, and Cosmetic Act of 1938 and its amendments.
5. Interpret what is meant by USP/NF.
6. Summarize the provisions of the Controlled Substances Act of 1970.
7. Contrast the responsibilities of the FDA and DEA.
8. Define orphan drug.
9. Define schedules of controlled substances and differentiate between C-I through C-V schedules.
10. State several responsibilities you have in administering medications as a direct result of the three major drug laws described in this chapter.

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## Complete List of Chapter Activities and Assessments

Refer to the Learning Objectives Mapping document, posted on the online resources, for a comprehensive guide to how this chapter's learning activities and assessments support the learning objectives.

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## Key Terms

**Controlled substances.** Drugs controlled by additional prescription requirements because of the danger of addiction or abuse.

**Drug Enforcement Administration (DEA).** A bureau of the Department of Justice that enforces the Controlled Substances Act.

**Drug standards.** Federally approved requirements for the specified strength, quality, and purity of drugs.

**Food and Drug Administration (FDA).** An agency within the Department of Health and Human Services that enforces the provisions of the Federal Food, Drug, and Cosmetic Act and amendments of 1951 and 1962.

**National Drug Code (NDC) Directory.** Provides the FDA with a list of all drugs manufactured for commercial distribution.

**Orphan drugs.** Drugs or biological products used for the diagnosis, treatment, or prevention of a rare disease or condition, that is, one affecting fewer than 200,000 persons in the United States, or greater than 200,000 persons where the cost of developing the drug is probably not recoverable in the United States.

**Over-the-counter (OTC) medication.** Medication available without a prescription.

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## Discussion Questions

You can assign these questions several ways: in a discussion forum in your LMS; as whole-class discussions in person; or as a partner or group activity in class.

1. Discussion: Drug Safety. Duration 60 minutes.
    a. In the United States, the use of marijuana has gained social acceptance, with some states legalizing the drug for recreational use or medicinal purposes. At the federal level, marijuana remains a Schedule 1 controlled substance by the United States Drug Enforcement Administration (DEA) and has not gained approval from the Food and Drug Administration (FDA) for medicinal use.
        1. What are the benefits to the consumer if this substance were to gain FDA approval?

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i. Answer: The discussion response answers need to include assurance of consumer safety because manufactures going through FDA approval will have demonstrated effectiveness and safety of their product.

2. What are the risks of not having FDA approval for marijuana medicinal use?
   i. Answer: The answer needs to include unwanted deaths or harm as seen with sulfanilamide and thalidomide.
3. What are the implications to the DEA schedule classification of marijuana if this substance obtains FDA approval?
   i. Answer: Because of the dynamic nature in medication use the DEA classifications have been revised or changed to incorporate those changes.

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## Additional Activities and Assignments

1. **Game**: The five schedules of controlled substances
   a. Using flip charts, whiteboards, or chalkboards, create two charts. Each chart should have five lists. Title the lists on each chart according to the five schedules of controlled substances. Using 4 × 6-in. index cards, make 104 flash cards that include two flash cards for each "Schedule Number," "Abuse Potential and Legal Limitations," and "Examples of Substances" found in Table 1-1, for a total of two sets of flash cards. Briefly introduce the learners to the schedules of controlled substances. Next, divide the learners into two teams. Provide each team with one set of the flash cards. Instruct each team to choose a leader. Each leader is to guide the team in a review of their flash cards, determination of the schedule that each flash card belongs to, and then tape each flash card in the appropriate column on its assigned chart. The teams have 7 minutes to complete this assignment. Review the answers with the learners, being inclusive of the information in Chapter 1. The team with the highest number of correct items wins. Provide the members of the winning team with a small prize.
2. **Presentation**: Legislative Acts
   b. Divide the learners into teams. Assign each team one of the legislative acts discussed in Chapter 1. Distribute pencils, erasers, markers, and poster boards to each team. Instruct each team to read the appropriate section in Chapter 1, create a poster, and prepare a short presentation. Each team will have 10 minutes to complete the task. Each team will then present their poster and information to the class. Briefly summarize the information presented to the learners, being inclusive of the information in Chapter 1.

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## Cengage Video Resources

- MindTap Videos Available for This Chapter:
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# Appendix

## Generic Rubrics

Providing students with rubrics helps them understand expectations and components of assignments. Rubrics help students become more aware of their learning process and progress, and they improve students' work through timely and detailed feedback.

Customize these rubric templates as you wish. The writing rubric indicates 40 points and the discussion rubric indicates 30 points.

## Standard Writing Rubric

| Criteria | Meets Requirements | Needs Improvement | Incomplete |
|---|---|---|---|
| Content | The assignment clearly and comprehensively addresses all questions in the assignment.<br>15 points | The assignment partially addresses some or all questions in the assignment.<br>8 points | The assignment does not address the questions in the assignment.<br>0 points |
| Organization and Clarity | The assignment presents ideas in a clear manner and with strong organizational structure. The assignment includes an appropriate introduction, content, and conclusion. Coverage of facts, arguments, and conclusions are logically related and consistent.<br>10 points | The assignment presents ideas in a mostly clear manner and with a mostly strong organizational structure. The assignment includes an appropriate introduction, content, and conclusion. Coverage of facts, arguments, and conclusions are mostly logically related and consistent.<br>7 points | The assignment does not present ideas in a clear manner and with strong organizational structure. The assignment includes an introduction, content, and conclusion, but coverage of facts, arguments, and conclusions are not logically related and consistent.<br>0 points |
| Research | The assignment is based upon appropriate and adequate academic literature, including peer reviewed journals and other scholarly work.<br>5 points | The assignment is based upon adequate academic literature but does not include peer reviewed journals and other scholarly work.<br>3 points | The assignment is not based upon appropriate and adequate academic literature and does not include peer reviewed journals and other scholarly work.<br>0 points |
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## Standard Discussion Rubric

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