

Nonprescription Drugs

OVER-THE-COUNTER DRUGS or OTC are considered safe and effective for use by consumers. They do not require a visit to a healthcare provider for a prescription. These products are usually located on the shelves in a drug store. Many of these products are found on the shelves of grocery stores, convenience stores, and large discount retailers. Common OTC medications are used to relieve aches and pains, itching, sore throat, and fever. Other types of nonprescription medicines prevent tooth decay and athlete's foot. The FDA is the agency that determines whether a medicine is safe enough to sell as an OTC medication. There are still risks associated with taking an OTC medication, so it is important to read and follow all directions.



Objective:



Summarize categories and types of nonprescription (OTC) drugs.

Key Terms:



analgesics
antipyretics
contraindication
dermatological
efficacy

Food and Drug
Administration (FDA)
gastrointestinal
legend drug
new drug application
(NDA)

nonprescription drugs
ophthalmic
OTC
over-the-counter drugs
therapeutic

Understanding Nonprescription Drugs

At one time, most drugs were available without a prescription. Before the creation of the **Food and Drug Administration (FDA)**—the federal agency of the United States Department of Health and Human Services (HHS)—responsible for protecting and promoting pub-

lic health by regulating food- and health-related products, drugs in the United States were not regulated. Medicines did not have to prove to be safe or effective to be marketed. According to the FDA, **nonprescription drugs** are medications “that are safe and effective for use by the general public without seeking treatment by a health professional.” Another name for nonprescription drugs is **over-the-counter drugs** or **OTC**. Nonprescription drug products play an increasingly vital role in America’s health care system.

To combat abuses in drug formulation, labeling, and market claims, a series of laws were enacted to regulate the development, distribution, storage, and dispensing of drugs. The Durham-Humphrey Amendment of 1951 established the distinction between a **legend drug** (a medication that requires a prescription) and an OTC drug (a medication that does not require a prescription).

NONPRESCRIPTION DRUGS

Nonprescription drugs can help people avoid unnecessary trips to the doctor.

OTC Medication Facts

Over the past few decades, the variety of OTC treatments available to consumers has expanded significantly. More than 700 OTC products on the market today use ingredients or dosages once available only by prescription. On average, individuals spend about \$338 per year on over-the-counter products.

OTC medicines provide 24-hour access to conveniently available healthcare options. Consumers rely on OTC medicines as a first response to minor ailments. In addition, OTC medications enable consumers to treat themselves when minor illness or injury occurs, avoiding an unnecessary visit to the doctor’s office. The availability of these medicines, without a prescription, provides relief for an estimated 60 million people who otherwise would not seek treatment.

Rx-to-OTC Switch Process

The process of transferring FDA-approved prescription medications to nonprescription or OTC status is known as the “Rx-to-OTC” switch. This process provides consumers with convenient and cost-effective access to safe and effective medicines without having to consult a healthcare provider.

Safety is a major concern when the FDA considers reclassifying a prescription drug as an over-the-counter item. Most ingredients used in OTC medications were typically marketed as prescription medications first.

New Drug Application (NDA) Process

Following a sufficient period of time in which the manufacturer collects appropriate scientific data on the product, the manufacturer can submit a new drug application (NDA). A **new drug application (NDA)** is the U.S. vehicle through which drug sponsors formally propose

that the FDA approve a new pharmaceutical for sale and marketing. FDA experts then review the application for safety and **efficacy**, which is the ability to produce a desired or intended result. Efficacy requires that the patient follow labeled directions on the container with regard to dose, frequency, precautions, and contraindications.

A **contraindication** is a symptom or condition that makes the use of a particular treatment or procedure inadvisable. For a medication to be granted over-the-counter status, the drug must have a wide safety margin and adequate product labeling written in easily understood terms. Considerations in reclassifying a drug as OTC are:

- ◆ Has the drug been used for a sufficient amount of time so any harmful effects are fully understood?
- ◆ What harmful effects (including those from misuse) may the drug cause?
- ◆ Is it a habit-forming drug?
- ◆ Do the benefits of OTC status outweigh the risks?
- ◆ Can the average person self-diagnose the condition that calls for the drug?
- ◆ Can the average person treat the condition without the help of a doctor or other healthcare professional?
- ◆ Can adequate directions for use be written?
- ◆ Can warnings against unsafe use be written?
- ◆ Can the average person understand the information written on the label?

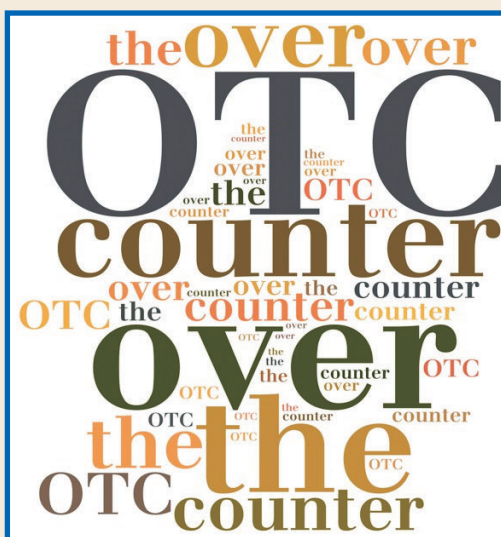


FURTHER EXPLORATION...

ONLINE CONNECTION: Know and Reduce Risks

Many physicians agree that responsible use of OTC medicines can help to ease the burden on medical providers. Many unnecessary appointments could be avoided by treating common ailments with OTC medications. However, sometimes OTC medicines can cause unpleasant side effects. Visit the FamilyDoctor website:

<http://familydoctor.org/familydoctor/en/drugs-procedures-devices/over-the-counter/otc-medicines-know-your-risks-and-reduce-them.html>



According to the FDA, nonprescription or OTC drugs are medications considered “safe and effective” for use without treatment by a health professional.

Benefits Associated with OTC Availability

Benefits include:

- ◆ Direct, rapid access to effective medicines
- ◆ Wide availability
- ◆ Decreased healthcare system utilization (e.g., fewer physician visits and lower healthcare system costs)
- ◆ Control over personal healthcare

Risks Associated with OTC Availability

Risks include:

- ◆ Potential for incorrect self-diagnosis that delays an accurate diagnosis and treatment of serious illnesses (e.g., delay in seeking advice from a healthcare professional)
- ◆ Increased risk of drug-to-drug interactions
- ◆ Improper use (could increase the risk of adverse events)
- ◆ Potential for misuse and/or abuse

Therapeutic OTC Drug Categories

More than 80 **therapeutic** (a treatment, a therapy, or a drug that helps heal a disease) OTC drugs can be grouped into 12 broad therapeutic classes. The classes are:

- ◆ **Analgesics** (pain relievers) and **antipyretics** (substances that reduce fever)
- ◆ Cold, cough, and allergy
- ◆ Nighttime sleep aids
- ◆ **Gastrointestinal** (products to treat the stomach and intestines)



FIGURE 1. OTC medicines are a trusted first line of defense for healthcare providers and consumers. Consumers must read the drug label facts on the medicine carefully to ensure they know the ingredients and understand any warnings and possible adverse effects.



FIGURE 2. It is important to know the active ingredients in your over-the-counter medications. For example, Tylenol® is a commonly purchased OTC with the active ingredient acetaminophen. Many other OTC drugs contain this active ingredient. Do not combine medicines with the same active ingredients as this could lead to serious health problems.

- ◆ **Dermatological** (products to treat the skin, hair, and nails)
- ◆ **Ophthalmic** (products used to treat the eyes)
- ◆ Oral health products (mouth)
- ◆ Menstrual products
- ◆ Nicotine replacement products
- ◆ Weight-loss products
- ◆ Vaginal contraceptives
- ◆ Other topical products: dermal and vaginal antifungal products

TABLE 1. Top-Selling OTC Drugs

Classes	Brands
Analgesics and antipyretics	Advil, Aleve, Tylenol, and Motrin
Cold, cough, and allergy	Zyrtec, Claritin, Alka Seltzer Plus, Allegra, Vicks Nyquil, Mucinex, and Robitussin
Nighttime sleep aids	Vicks Nyquil Zzzquil liquid, Vicks Nyquil Zzzquil tablets, and Unisom Sleep gels
Gastrointestinal products	Prilosec, Zantac, Pepcid, Tums, Mylanta, Maalox, Imodium, Pepto Bismol, and Gas-X
Dermatological products	Retinol, Benzoyl, Cortizone, Neosporin, Benadryl, and Nix
Ophthalmic products	Refresh, Systane, Opti Free, Visine, and Zaditor
Oral health products	Orajel, Anbesol, Crest, Colgate, Biotene, Scope, and Abreva
Menstrual products	Midol, Estroven
Nicotine replacement products	Varenicline, NicoDerm, and Nicorette
Weight-loss products	Garcinia Cambogia, Alli, and Hydroxycut
Vaginal contraceptives	Today Vaginal Sponge, Vaginal Inserts, and Conceptrol Vaginal Contraceptive Gel
Dermal and vaginal anti-fungal	Lotrimin, Lamisil, Vagisil, and Fungi Nail

FAQs ABOUT NON-PRESCRIPTION DRUGS

Non-prescription drugs are used to treat a variety of common ailments.

Common Nonprescription Drug Questions and Answers

The following information contains questions and answers that may be relevant to you at some point.

Headache

There are so many options to relieve headache pain. Which one is the best? OTC pain medications include acetaminophen, ibuprofen, and naproxen. None of these has been proven to be more effective than another, but some people find that one works better for them.

Pain Medication

I have heard that pain medication can cause ulcers. Am I at risk if I only use these occasionally? Ibuprofen and naproxen can cause stomach problems. Taking the medications with food or a snack can help. With occasional use, most people do not experience major problems.

Diarrhea

What can I do for diarrhea? It is important to drink plenty of clear liquids and to avoid dairy products, caffeine, and alcohol. An OTC anti-diarrheal medication (e.g., Imodium or Pepto-Bismol) should be taken.

Insomnia

What can I take to help me fall asleep? It is essential to maintain good sleep habits (e.g., sticking to a regular bedtime and getting regular exercise). Then a person can take an OTC sleep aid, such as Unisom Sleep Gels.

Lice

How will I know if I have head lice? Will the whole family get lice? The telltale sign is an itchy head. If family members do not share personal items, the lice should not spread.

Poison Ivy

Is my poison ivy contagious? The rash does not pass from person to person.

Cold or Flu

What is the difference between a cold and the flu? A cold has a slow onset with a runny nose, sneezing, sore throat, and cough. The flu has a rapid onset with a fever, headache, muscle aches, exhaustion, and occasional runny nose, sneezing, and sore throat. A cough is common with the flu and can be severe.

Flu Medication

Is there a medication I can take for the flu? Tamiflu is a medication used to treat people with the flu.



FIGURE 3. OTC sleep aids can be effective for an occasional sleepless night. They are a temporary solution to insomnia and are intended for use no longer than two weeks. Some OTC medicines can leave you feeling groggy and unwell the next day.

Athlete's Foot

What is the best treatment for athlete's foot? Keep your feet clean and dry. Also, avoid walking around barefoot, and apply an anti-fungal, such as Lamisil.

Coughing

Should I take a cough suppressant for my cough? Medicines that claim to suppress a cough or stop phlegm are not usually recommended.

Indigestion During Pregnancy

I am pregnant and have indigestion. What can I take to relieve it? It is best to take magnesium-based liquid antacids, such as Mylanta or Maalox.

Mosquito Bites

How can I stop my mosquito bites from itching? An antihistamine, such as Benadryl, or a cream containing an antihistamine can be applied directly on the bites.

Back Injury

I hurt my back. What can I do to make it feel better? An anti-inflammatory product, such as ibuprofen, should be taken. Then take a warm bath in Epsom salts, and restrict strenuous activities.

Cuts

I cut my finger. What should I put on it, and should I use a bandage? An antibiotic ointment, such as Neosporin, should be used on the cut. It should be covered with a bandage that is changed daily.



FIGURE 4. Athlete's foot (tinea pedis) is a contagious fungal infection that affects the skin on the feet (damaged skin between and under the toes). Athlete's foot can be treated with OTC topical antifungal medications.



FIGURE 5. A variety of OTC products are available for the self-treatment of minor wounds. Some examples of OTC wound care products are topical antibiotics, irrigants, antiseptics, various types of bandages, and products that reduce the appearance of scars.

Summary:



Over-the-counter medicines are easily accessible to most consumers. The availability of OTC medicines provides relief for many people who would otherwise not seek treatment. Most consumers use nonprescription drugs as a first response to minor ailments, thus eliminating unnecessary visits to the doctor's office. OTC medicines empower individuals and families to meet their daily healthcare needs.

Checking Your Knowledge:



1. Differentiate between over-the-counter and prescription medications.
2. Describe the process of transferring FDA-approved prescription medications to nonprescription over-the-counter status.
3. List six considerations when reclassifying a prescription medication to an OTC medication.
4. Explain the benefits and risks of using OTC medications.
5. List the 12 broad therapeutic classes of OTC medications, and give an example from each class.

Expanding Your Knowledge:



Ask a local pharmacist if you can interview him or her about OTC medications. Then ask the pharmacist to list the most commonly requested OTC products. Ask him or her the pros and cons of OTC medications versus prescription medications.

Web Links:



Drug Facts

<https://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications>

Over-the-Counter Medicine Safety

<http://www.scholastic.com/otc%2Dmed%2Dsafety/>

OTC Medicine Safety

<http://www.aapcc.org/prevention/over-counter-medicine-safety/>

OTC Use

http://www.bemedwise.org/brochure/bemedwise_english_brochure.pdf