



UNDERSTANDING THE DIFFERENCE

Generic vs. brand name drugs.

What is a generic drug?

A generic drug is identical (or bioequivalent) to a brand name drug in intended use, dosage, strength, effectiveness and safety. For a generic drug to be approved, it must meet the same quality standards as the brand name product. Even the generic manufacturing, packaging, and testing sites must meet the same standards. Many generics are produced in the same manufacturing plant as their branded counterparts.

Are generics as effective as the brand?

Yes. Generic drugs are required by the Food and Drug Administration (FDA) to have the same active ingredient, strength, dosage form, and route of administration as the branded product. The FDA ensures this via thorough testing and review of bioequivalence data.

How does a generic drug differ from a brand?

The major difference between a generic and brand name drug is the price. Most generics cost 70% to 90% less than the brand, thereby saving consumers an estimated \$8 billion to \$10 billion a year at pharmacies. Billions more are saved by hospitals using generics. A generic drug also may differ from a brand in terms of shape, color or packaging, but these differences only affect how the medicine looks, not how it works.

Why are generics cheaper?

Brand name drugs are expensive because they don't have any competition to drive their price down. But when patents on brand name drugs near expiration, other manufacturers can apply to the FDA to sell generic versions. Because the generic manufacturers are not required to repeat costly clinical trials and generally do not incur advertising, marketing and promotional costs, they're able to sell their product for much less. Conversely, companies that make brand drugs have often spent huge amounts on research, development and advertising and must price their drug at a cost high enough to recoup their spending and turn a profit. Additionally, when more than one company makes generic versions of a drug, it creates competition in the marketplace, further lowering prices. These savings are passed on to you, the consumer, in the form of lower copays.

How do I get generic drugs? Will my doctor prescribe them?

The generic substitution laws in the U.S. vary by state. Some state boards of pharmacy have instituted mandatory generic substitution laws, where pharmacists will substitute a generic, when available, for a brand-name medication. Some states require the patient's consent prior to substituting a generic for a brand. So the generic version of the prescribed drug may be dispensed automatically, or only with your approval or if you request it. Private and government insurance companies often promote using generic drugs whenever possible to lower costs. Also, doctors are more apt to prescribe generics because they want their patients to have drugs that are as safe and effective as branded medications, but are more affordable.



If generic drugs are so great, why are brand name drugs prescribed at all?

By law, generic drugs cannot be sold until the brand name drug's patent expires, which could take 10 years or more. Brand names are prescribed in cases where generic versions are not yet available.

I've always received the generic version of my medication, so why did I get a brand?

Sometimes when a generic is introduced, it encourages price competition between the brand and the generic manufacturers, and occasionally the brand drug price ends up being less than the price of the generic. When this happens, insurance companies and health plans are able to share the savings with you by substituting a brand name drug for the same copay as the generic. Then, when circumstances and prices change, you're automatically switched back to the lower-cost generic.

Facts about Generic Drugs.* U.S. Food and Drug Administration, <http://www.fda.gov/drugs/resourcesforconsumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>

Generic Drugs: Questions and Answers. U.S. Food and Drug Administration, <http://www.fda.gov/drugs/resourcesforconsumers/questionsanswers/ucm100100.htm>

Peter R. Kongstvedt, Essentials of Managed Healthcare, 6th Edition, Jones & Bartlett Publishers, 2012, pg 267 *Generic Drugs: Same Medicine, Lower Cost.* U.S. Food and Drug Administration, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm340343.htm>