

Frequently Asked Questions about Generics

What is a generic medicine?

Generic drugs contain the same active ingredients, in the very same strength, as brandname drugs. When a medicine is first developed, the pharmaceutical company that discovers and markets it receives a patent on its new drug. The patent usually lasts for 20 years, to give the originating company a chance to recoup its research investment. After the patent expires, a generic version of the drug may become available. Generics are marketed under the drug's chemical, or "generic," name and meet the same U.S. Food and Drug Administration (FDA) quality and effectiveness standards as the original.

Are generic drugs as good as brand-names?

Generic pharmaceutical manufacturers must prove to the FDA that their version of a drug:

- · contains the same active ingredient;
- is identical in strength, dosage form, and route of administration;
- has the same indications, dosing, and labeling; and
- provides the same efficacy and safety profile to patients ("bioequivalent").

Are generic drugs safe?

Generic medicines have to be safe and effective to be approved by the FDA. The FDA also requires generic drug manufacturers to:

- meet the same batch-to-batch requirements for strength, purity, and quality as the original manufacturer and
- follow the same strict "Good Manufacturing Practices" rules.

Why do generic drugs look different than the brand-name product?

U.S. trademark laws don't allow generic drugs to look exactly the same as another drug already on the market. For that reason, the color and shape of a generic pill may be different than the brand-name. Sometimes it will have a different coating or flavor. These "inert ingredients" also are carefully considered by the FDA. Differences in taste or appearance do not affect the drug's safety or effectiveness.

Why are generics cheaper?

Some brand-name manufacturers charge customers higher prices in the United States than they do in other countries, where drug prices are regulated. Drug research is costly,

and patent protection gives brand-name manufacturers at least 20 years to recover those costs—costs that generic manufacturers do not have. Brand-name manufacturers collectively spend billions of dollars in marketing new drugs to doctors and the public; they send their representatives to visit with doctors in their offices; and they pay for physicians' trips to meetings and conferences to talk about their drugs with other doctors. Generic manufacturers rarely spend money on advertising and marketing—another important way they keep their costs down.

How large are these price differences?

According to the National Association of Chain Drug Stores, in 2007, the average retail price of generic prescription drugs was \$34.34. The average retail price of brand-name drugs was more than three times higher: \$119.51.

Aren't newer drugs better?

Not necessarily. Sometimes they are, but often they are no more effective than the triedand-true drugs we already have. Marketing is used to try and convince both doctors and patients that new, expensive drugs are better, and they frequently are not. Occasionally, new drugs end up causing serious side-effects that were not discovered in their initial testing. Just because a product costs more does not mean it is better for you!

Are generic drugs made by the same companies that make brand-name drugs?

In some cases, yes. Brand-name companies make about half of generic drugs.

Is a generic drug available for my brand-name prescription?

The easiest way to find out is simply to ask your doctor or pharmacist. There are also online resources, such as those listed at the right.

Helpful Tools

Check for Savings

A tool from DrugDigest to find out whether a generic version of your prescribed drug is available.

http://www.drugdigest.org/ Click Interactive Tools, Click "Check for Savings"

Drugs@FDA

A search tool from the Food and Drug Administration to help you identify whether your brand-name drug has any "therapeutic equivalent" versions. http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

GPhA's Guide to Finding Generics

The Generic Pharmaceutical Association has created this step-by-step guide to make it easier to use and understand the FDA database, above. http://www.gphaonline.org/AM/Template.cfm?Section=FAQs&Template=/CM/Cont...

Recent Generic Approvals

This website includes a list of generic drugs recently approved by FDA. Note that they may not yet be available in your local pharmacy. <u>Find that list here</u>.

Find Out More

Information for Consumers: Generic Drugs (también en español)

Questions and Answers

From the Food and Drug Administration

http://www.fda.gov/cder/info/consumer_generic.htm

http://www.fda.gov/cder/consumerinfo/generics_q&aSpanish.htm

FDA Ensures Equivalence of Generic Drugs
From the Food and Drug Administration
http://www.fda.gov/cder/consumerinfo/generic equivalence.htm - equivalence



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