Fast Facts on Generic Drugs

The latest styles are always tempting. Buying new cars, clothes, or computer upgrades may hurt your budget, but buying the newest drugs could hurt both your wallet and your health. For prescription medicine, "classic" drugs may be the way to go. This fact sheet will tell you why.

New drugs have unknown risks. Of course, drugs are tested before marketing, but they may not be tested in elders, children, or people with chronic medical conditions such as diabetes or asthma. Problems may be revealed after a drug is used in more people, or in a more diverse population. A new drug may be tested for a few months, but prescribed for years. Long-term problems – and drug interactions – take a while to show up.

One way to protect yourself from the unknown risks of new drugs is to request generic drugs. About three-quarters of FDA-approved drugs have generic equivalents. If you can buy a drug in generic form, it has been available on the market for many years. Generic drugs are time-tested, so we know more about their risks and benefits.

So, what are generic drugs, anyway?

Generic drugs are chemically identical to brand name drugs in every way: dose, safety, strength, how the drug is meant to be taken, quality, intended use, and bioavailability. Only the price is different, and the fact that they are sold under their chemical name. Generic drugs are less expensive than brand name drugs because generic manufacturers don't bear the investment costs of new drug development.

New drugs are developed under patent protection. The patent protects a company's investment in research, development, and marketing by giving the company the sole right to sell the drug while the patent is in effect. The Food and Drug Administration (FDA) is the U.S. government agency responsible for protecting the public health by assuring the safety of medical drugs for the conditions they treat. As patents near expiration, manufacturers apply to the FDA to sell generic versions. Generics manufacturers haven't paid for developing a drug, so they can sell their product at reduced prices. Generic competition usually results in lower prices on the brand-name version as well. By the way, brand name manufacturers make about half of generic drugs.

Aren't generics inferior to branded drugs?

No. Generic drugs are subject to the same FDA standards as all drugs and must be manufactured in factories that also meet FDA regulations. Generic drugs must pass stringent "bioequivalency" tests, in humans, that compare blood levels of the generic with the brand equivalent. The minor variability in drug levels allowed in these comparative tests is the same standard that different batches of a branded drug must meet. After a generic drug goes on the market, the FDA continues to monitor drug quality and investigates any reports of generic drugs – or branded drugs – failing to meet standards.

Product failures are unusual, but have occurred with both branded and generic drugs. If you're sure that any version of a drug you're taking isn't working, tell the FDA. You don't have to be a doctor to report any problem with a drug to the FDA's Medwatch program. There is an easy to use form on the FDA's website http://www.fda.gov/medwatch; complaints can also be submitted by phone 1-800-FDA-1088 or fax 1-800-FDA-0178. If possible, the lot number, expiration date, and basis for suspecting failure should be included, and samples of the drug should be kept in case they are needed for testing.

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What are the main differences between generic drugs and brand-name drugs?

On average, a prescription for a branded drug costs three times as much as a prescription for a generic drug*. Besides price, the main difference is the packaging – both in the appearance of the containers and the way the pills look. Due to trademark laws, generic and brand-name drugs cannot look identical, so generic pills are often a different color or shape from their counterparts. Excipients, which include fillers, binders, colors, and coatings, may differ in various versions of a drug. It's possible that an individual could be allergic or sensitive to a specific excipient, but that could be true of either branded or generic drugs. There aren't that many excipients, so drug manufacturers choose excipients from the same limited pool. It is the final form of the generic that is tested against the brand, so if an excipient reduced absorption, the generic would fail the comparative test with the brand.

What if a drug isn't available as a generic?

Some novel drugs are still under patent protection, so are not available as generics. If your doctor feels that it is important for you to take a particular brand name product, ask why. If the brand name product has a proven added medical benefit for you, the extra cost and risk may be justified. If the only advantage is having to take one or two fewer pills or that the brand name product comes with additional services provided by the manufacturer, you may decide that these benefits are not worth the extra money.

"New" drugs are not necessarily novel drugs. That's because many "new" drugs are minor variations of older drugs, new formulations (for example, long-acting forms) or combinations of older drugs. Buying the original version of a drug, or buying generics of the separate components of a branded combination drug, is almost always less expensive. If a generic is not available, it may be worth saying to your doctor, "I'd rather not use a new drug. Is there a generic available for this drug or another in its class?" A great source for information on generics is *Consumer Reports Best Buy Drugs* at http://www.consumerreports.org/health/bestbuy-drugs.htm.

What is the bottom line?

Major drug companies would have you believe that the newest, brand-name drugs are best, and have used implicit and explicit tactics to discourage consumers from asking for generic and other classic drugs. Demanding older, classic drugs will not only personally save you money, it will help drive down health care costs. It may even decrease your chances of drug-related adverse effects. Taking classic drugs is a sound health care decision. Don't let fancy packaging and glossy ads tell you otherwise.

*Prescription Drug Trends, May 2007. Kaiser Family Foundation, http://kff.org.

The National Women's Health Network—one of the few consumer advocacy groups that takes no money from pharmaceutical companies—improves the health of all women by developing and promoting a critical analysis of health issues in order to affect policy and support consumer decision-making.

PharmedOut is an independent, publicly funded project that empowers physicians to identify and counter inappropriate pharmaceutical promotion practices.