



patient education: Generics

Prescription drugs can be a costly part of your medical expense. Americans spend billions of dollars on prescription drugs each year. One thing you can do to help control health care costs is to consider taking generic medications. Generic drugs may offer you a better value, while still being safe and clinically effective. And in most cases, generic drugs are available for a lower copay. A number of questions and concerns have been raised about the quality of generics as compared to brand name products, and you may wonder whether or not you should take them. The following are answers to some of the more commonly asked questions regarding generic drugs. We hope this will answer most of your questions and address any concerns you may have regarding generic drugs.

WHAT IS A GENERIC DRUG?'

A new drug is given two names. One is the brand name, which is what the manufacturer chooses to call the product. The other is the generic name, which is the name of the chemical compound of the drug. Every drug has a generic name to describe its active ingredient.

ARE GENERIC DRUGS EFFECTIVE?'

To gain Food and Drug Administration (FDA) approval, a generic drug must have the same effect on the body as the brand name product. This means that the generic product must have the same active ingredient, must be the same strength, and act the same way in the body as the brand name product. Sometimes, the generic drug may have a different color or shape than the brand name drug. Differences like these do not have any effect on the action of the drug; however, they do help to distinguish one product from another.

ARE GENERIC DRUGS SAFE?'

The role of the FDA is to ensure that all new brand and generic drugs are safe and effective. Serious side effects are reported to the FDA by doctors, pharmacists, nurses and other health professionals. All drugs, regardless of whether they are brand or generic, may present side effects.

WHY ARE MOST GENERIC DRUGS LESS EXPENSIVE THAN BRAND NAME PRODUCTS?'

Brand name drugs are usually given patent protection for 20 years from the date of submission of the patent.' The patent protects the drug company's right to be the only manufacturer of that drug. After the patent expires, other companies can then manufacture and sell the drug under either a different brand name or the generic name. Because of lower research costs and more competition, the generic product is usually sold at a lower price than the original brand name product. It is interesting to note that the price of many brand name drugs does not reduce when generic products become available.

WHO MANUFACTURES GENERIC DRUG PRODUCTS?

Many drug companies that manufacture brand name products also manufacture generic products. In fact, many drug companies that manufacture the brand name products also own the company that makes the generic version of their drug.

HOW ARE GENERIC DRUGS APPROVED FOR USE?

The FDA reviews all brand name and generic products for safety and effectiveness. Before a generic drug is approved for use in the United States, the drug company must provide proof to the FDA that the product has the same active ingredient as the brand name product. In addition, the generic product must meet FDA standards for the amount of active ingredient and the extent to which it is absorbed into the body. When the generic product meets these standards, it is considered therapeutically equivalent to the brand name product.¹

WHY DO HEALTH PLANS HAVE GENERIC DRUGS ON THEIR FORMULARIES?

Generic drugs are safe, effective, and are often less expensive than brand name products. Generic drugs save consumers from \$8 to \$10 billion a year at retail pharmacies.² The FDA states that the average cost of a typical generic costs 50 - 70% less than its branded counterpart.³

Feel free to discuss the generic drugs with your doctor or pharmacist the next time you need to fill a prescription. When you have your prescription filled with a generic, you can be sure you are getting the quality medication you need at a better value.

To learn more about generic drugs, you can contact the FDA at 1-888-INFO-FDA, or visit the FDA Center for Drug Evaluation and Research, Office of Generic Drugs website at: <http://www.fda.gov/cder/ogd/index.htm>

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