Frequently Asked Questions About Generic Drugs

**What are generic drugs?**
A generic drug is a copy of a brand-name drug with the same active ingredients and requirements such as dosage, safety, strength, how it is taken, quality, performance and intended use. After a brand-name drug’s patent expires, generic drugs become available to consumers at a lower cost.

**Are generic drugs as safe as brand-name drugs?**
Yes. The Food and Drug Administration (FDA) requires that all drugs be safe and effective. Since generics use the same active ingredients and are shown to work the same way in the body, they have the same risks and benefits as their brand-name counterparts.

**Are generic drugs as strong as brand-name drugs?**
Yes. The FDA requires generic drugs to have the same quality, strength, purity and stability as brand-name drugs. The FDA won't permit drugs to be made in substandard facilities. The FDA conducts about 3,500 inspections a year to ensure standards are met. Generic companies have facilities comparable to those of brand-name companies. In fact, brand-name companies are linked to an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name.

**Are generic drugs tested as thoroughly as the brand-name versions?**
Yes, the FDA requires a generic drug to be tested to meet equivalency standards. These tests require that the generic drug’s performance and active ingredients are the same as the brand-name drug. This includes quality, strength, purity and stability. The generic drug must list the same warnings and side effect information as the brand-name drug. However, generic drugs do not have to go through the clinical trials because the brand-name drug has already completed the testing.

**Does every brand-name drug have a generic version?**
No, not until a brand-name's patent expires. Brand-name drugs are generally given patent protection for 20 years from the date of submission of the patent. This provides protection for the innovator who laid out the initial costs (including research, development and marketing expenses) to develop the new drug. However, when the patent expires, other drug companies can introduce competitive generic versions, but only after they have been thoroughly tested by the manufacturer and approved by the FDA.

**So, why choose generic drugs?**
Bottom line, generic drugs can save you money and help keep costs down for everyone. Both brand-name and generic drugs have the same active ingredients, strength and dosage. Generic drugs are safe, effective and FDA-approved. Talk with your physician or pharmacist to determine if a generic drug is available for the brand-name drug you are taking.

**Why are generic drugs less expensive?**
Generic drugs are less expensive because generic manufacturers don't have the investment costs of research, development and marketing of a new brand drug. New brand drugs are developed under patent protection. The patent protects the investment by giving the company the sole right to sell the drug while it is in effect. As patents near expiration, manufacturers can apply to the FDA to sell generic versions. Once generic drugs are approved by the FDA, there is greater competition, which keeps the price down. Today, almost half of all prescriptions are filled with generic drugs.

**If brand-name drugs and generic drugs have the same active ingredients, why do they look different?**
In the United States, trademark laws do not allow a generic drug to look exactly like the brand-name drug. However, a generic drug must duplicate the active ingredients. Colors, flavors and certain other inactive ingredients may be different.

**Are brand-name drugs made in more modern facilities than generic drugs?**
No. Both brand-name and generic drug facilities must meet the same standards of good manufacturing practices. The FDA won't permit drugs to be made in substandard facilities. The FDA conducts about 3,500 inspections a year to ensure standards are met. Generic companies have facilities comparable to those of brand-name companies. In fact, brand-name companies are linked to an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name.
Quick Facts About Generic Drugs

The use of generic drugs adds value to your healthcare dollar. Talk to your physician or pharmacist about whether generic drugs are available for the brand-name drugs you are taking.

• A generic drug is made with the same active ingredients and is available in the same strength and dosage as the equivalent brand-name drug.

• Before a generic can be labeled as equivalent to the brand-name drug, it must meet stringent standards set by the Food and Drug Administration (FDA).

• A generic drug provides the same therapeutic effects as its brand-name counterpart.

• Based on average ingredient cost, generics can save as much as 85 percent over their brand-name counterparts.

Some drugs do not have generic equivalents, but many have generic alternatives that may work for you. Remember to ask your physician or pharmacist if a generic alternative is available for your prescription.

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What is the best source of information about generic drugs?

Contact your physician, pharmacist or Blue Cross and Blue Shield of Alabama for information on your generic drugs. You can also visit the FDA web site at www.fda.gov/cder/ogd/index.htm for more information.

What is Generic Initiative for Value and Efficiency (GIVE)?

On October 4, 2007, the FDA launched the Generic Initiative for Value and Efficiency, or GIVE. The initiative will use existing resources to help the FDA modernize and streamline the generic drug approval process. More information can be found at: www.fda.gov/oc/initiatives/advance/generics.html.


www.bcbsal.com/generics

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