



## Generic Medication:

*Did you know that nearly 90% of the prescriptions filled in the United States are filled with generic medications?*

As common brand name medications continue to lose patent protection, that number should continue to increase. Although generic medications are used to fill most of the prescriptions in the United States, there are still misconceptions surrounding them.

### What is a generic medication?

Medications can have up to 3 names; a chemical name (scientific name), a generic name, and a trade (or brand) name. Both the generic and trade name are recognized in the pharmaceutical industry. When a medication is initially approved by the FDA, it is given a set number of years, usually 20 years from when the drug application is initially submitted. After this time period elapses, other manufacturers can submit an application to the FDA to bring generic versions of the drug to market. These generic versions contain the identical active ingredient as the brand name medication in the same strength and dosage form.

### Are generic drugs safe and effective?

The FDA requires generic medications to meet the same requirements for strength, purity, and quality as the brand name manufacturer. Generic companies must also comply with the same strict current Good Manufacturing Practices (cGMP) rules that regulate the entire production process. Generic medications must be shown to “bioequivalent” to the brand name product. Bioequivalence means that the generic product is absorbed in the body at the same rate and to the same extent in order to produce the same therapeutic effect as the brand name drug. Batches of generic medications are subject to the same testing and requirements that are applied to batches of brand name drugs. Since the brand name medication has already undergone the studies to show the

medication is safe, generic companies are not required to complete clinical trials or other testing so show the active ingredient is considered safe. The bioequivalence testing is what is most important to show that the generic drug will produce the same effects in the body as the reference brand name drug.

### How can generic medications differ from brand name drugs?

While generic drugs are required to contain the same active ingredient and product the same therapeutic effects in the body, they can differ from the brand name in some ways. These often include things such as:

- ▲ Shape
- ▲ Color
- ▲ Packaging
- ▲ Inactive ingredients (fillers, dyes)

The above differences in no way affect how the drug works in the body, but rather are due to manufacturing procedures and/or trademark reasons. Any inactive ingredients that are used in either brand or generic products must be considered safe by the FDA.

### Who makes generic medications?

Years ago there were many generic manufacturers. As time went on, manufacturers have merged or in some cases have been purchased by brand name manufacturers. At this time generic medications are produced by both generic and brand name manufacturers.

When a patent expires for a brand name medication, the first generic that is approved is given 6-months of exclusivity in the prescription drug market. That means other generic manufacturers must wait that time period before they can begin to distribute their approved generic medications. This is one of the reasons that prices for new generic medication do not fall until several months after they are launched.

### How do generic drugs impact my out-of-pocket costs or the costs to my prescription benefit plan?

Often times the copayment for generic medications will be significantly less than that of brand name medications. In addition, generic medications are less expensive than brand name medications so this helps your employer-sponsored prescription drug plan save money. Therefore choosing generic medications where appropriate helps both you and your health control prescription drug costs, while still offering high-quality treatment options for your conditions.



For further information, please visit:  
<https://www.fda.gov/Drugs/default.htm>