



Consortium of Multiple Sclerosis Centers

What You Need to Know About Generic Medications

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What is a generic drug?

A generic drug is an identical reproduction of a brand-name drug in dosage, safety, strength, quality, intended use, and how it is taken. Generic drugs also must work in the body the same way as the original brand name products. Manufacturers can apply to the Food and Drug Administration (FDA) to sell generic versions when the patent of the brand-name medication is close to expiration.

What are the FDA requirements for generic drugs?

The Food and Drug Administration, or FDA takes many steps to ensure that generic drugs are safe to use in place of the brand name versions.

1. The generic medication must contain the same active ingredient. The dosage form and route of administration must be identical. For example, if the brand-name drug is a capsule, the generic version must also be a capsule. The generic version must also be the same dose strength as the brand name drug.
2. The generic version of the medication must be “bioequivalent” to the brand-name version. This means the amount of active drug that reaches the bloodstream and the amount of time for the drug to reach the bloodstream cannot be “significantly” different in patients who take the generic version compared to patients who take the brand-name version.
3. The generic medication must have the same labeling as the brand-name medication.
4. The manufacturer must prove to the FDA that the generic medication and the raw materials used to produce it meet the United States Pharmacopoeia or USP standards for purity. The USP is the organization that sets standards for drug purity.
5. The manufacturer must prove that the generic version is stable and that the drug’s container will not interact with the drug.
6. The manufacturer must show that the facilities used to make the generic drug meet federal regulations about good manufacturing practices and pass an inspection by the FDA.

Administrative Office

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How are generic drugs and brand name drugs different?

Generic drugs must look different than brand-name drugs because of patent laws. The colors, flavors, and inactive ingredients of generic drugs may be different from those in the brand-name version. Patients who have allergies or side effects from dyes may react differently to generic products.

When should I not switch from generic to brand-name medications?

If you take a medication that requires checking drug levels in the blood, you should not switch between the generic and brand-name versions. Some medications that require this type of monitoring are warfarin (Coumadin), digoxin (Lanoxin), and several medications used to treat seizures such as phenytoin, carbamazepine, valproate, and phenobarbitol. The slight variations between the generic and brand-name versions may increase or decrease the drug levels, making it difficult to adjust the dose correctly.

How can I tell if my medication is generic or brand-name?

Your doctor can specify whether the pharmacist is allowed to dispense a generic version of the medication you are prescribed. The pharmacist should tell you if a generic medication has been dispensed in place of a brand-name product. The names of both medications are included on the label of the prescription bottle. Ask your pharmacist if you have any questions about which version you are getting.

About the Author:

Kristen Jefferies is currently working as the Clinical Pharmacist in the Neurology Clinic at the University of Utah Hospitals and Clinics.

She recently completed a pharmacy practice residency at the University of Utah. Kristen completed her pre-pharmacy requirements at Utah State University and earned her Doctor of Pharmacy degree at the University of Utah in Salt Lake City, Utah.

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