

# Generic Drugs: What Parents Need to Know

#### What are generic drugs?

Generic drugs are usually lower cost alternatives of brand-name drugs that have the same active ingredient and dosage form and work in the same way as their brand-name counterpart. They may however, have a different size, color or shape because some of the non-drug ingredients (e.g. flavoring, coloring agents) may be different. Some generic drugs are even made by the brand name manufacturer, but they are just sold as a lower cost alternative. Most generic drugs, though, are made by other manufacturers who have received approval by the US Food and Drug Administration (FDA) to sell their generic alternative.



#### A generic drug is identical to a brand name drug in the following ways:

- · Dosage form
- Safety
- Strength
- · Route of administration
- Quality
- Performance characteristics
- · Intended use

# Why are generic drugs important?

The availability of generic drugs helps increase competition and lowers the cost of medications. Use of generic drugs may reduce your prescription insurance co-payment (/English/family-life/health-management/health-insurance/Pages/Understanding-Cost-Sharing-Deductibles-Copayments-Coinsurance.aspx). Ask your pediatrician whether a generic alternative is available for your child's medication and if it is an appropriate alternative.

### Why do brand-name drugs cost more?

Companies that produce brand-name medications invest money in the research, development, and marketing of new drugs. They price these drugs higher to recover some of these costs. New drugs are protected by patents from being produced in a generic form by other companies. When the patents or other periods of exclusivity on a brand-name drug expire, other companies may apply to the FDA to sell a generic version. Since generic drug makers do not develop a drug from scratch, the costs to bring the drug to market are less; therefore, generic drugs are usually less expensive than brand-name drugs.

# What is the Food and Drug Administration (FDA) approval process for generic drugs?

All drugs, both brand and generic, approved by the US Food and Drug Administration must meet the same high standards for quality, strength, purity, and stability. Generic competitors may submit an application to sell a generic version of a brand drug when the patent or other periods of exclusivity on a brand-name drug expires. The FDA must review and approve the generic drug application before the drug is made available to the public. The generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs

# What is a preferred drug in my formulary (/English/family- Back to Top life/health-management/health-insurance/Pages/Your-Health-Plans-Formulary.aspx)?

Preferred drugs are those that are covered by your insurance company (/English/family-life/health-management/health-insurance/Pages/Things-to-Consider-When-Evaluating-Health-Insurance-Plans.aspx) and do not need your pediatrician to call the insurance company for authorization. If your pediatrician prescribes a non-preferred drug, he or she or his or her representative will need to contact your prescription insurance provider to get approval for the drug to be covered. This can be done via phone, fax, or email.

#### Are generic drugs as effective as brand-name drugs?

Yes. A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken, and the way it should be used.

# What if my child is allergic to a generic drug?

Since brand-name drugs and generic drugs have the same active ingredient, it is very likely that if you are allergic (/English/safety-prevention/at-home/medication-safety/Pages/Medication-Side-Effects.aspx) to the brand-name drug, you will also be allergic to the generic drug and vice-versa. In this situation, you will need to take an alternate drug. Your insurance company should cover this.

# How do I know if I am receiving a "generic" drug from my pharmacy?

Pharmacies often substitute a brand-name drug for a generic drug unless state law does not allow it. If your pediatrician writes "Dispense as written" on your prescription, then your pharmacy cannot dispense a generic drug to you for your child. Your pediatrician may do this if he or she feels that the generic drug is not right for your child.

## Is there a "generic" for every brand-name drug?

**No, not every brand-name drug has a generic drug.** When new drugs are first made they have drug patents. The patent, which protects the company that made the drug first, doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

#### Talk with Your Pediatrician

You should discuss any questions or concerns you have with your pediatrician. He or she will help determine whether a generic medication is appropriate for your child.

#### Additional Resources:

- Your Health Plan's Formulary (/English/family-life/health-management/health-insurance/Pages/Your-Health-Plans-Formulary.aspx)
- Understanding Cost Sharing: Deductibles, Copayments & Coinsurance (/English/family-life/health-management/health-insurance/Pages/Understanding-Cost-Sharing-Deductibles-Copayments-Coinsurance.aspx)
- Antibiotic Prescriptions for Children: 10 Common Questions Answered (/English/safety-prevention/at-home/medication-safety/Pages/Antibiotic-Prescriptions-for-Children.aspx)
- Retail Based Clinics: Information for Parents (/English/family-life/health-management/health-insurance/Pages/Retail-Based-Clinics-Information-for-Parents.aspx)
- Understanding Generic Drugs
   (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm) (FDA.gov)

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