

Generic Medications

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Because there are no government programs to subsidize pet healthcare, and pet insurance is still in its infancy, the burden of cost for medications falls entirely on the pet owner. With the costs of medicines escalating, there are more questions regarding the use of generic medications. Most veterinarians use a combination of human, veterinary-only, and compounded medications for your pet's medical condition. For many of your pet's medications, generics are available to save money without compromising your pet's health.

Q. Are generic drugs equivalent to brand name drugs?

A. Yes. Generic equivalents of brand-name drugs have the same active ingredients and potency, are often available in the same dosage forms (for example, tablet, liquid, or injectable), and have been demonstrated to be as safe and effective as the original product. Although inactive ingredients such as fillers and dyes can be different, these ingredients should not affect the efficacy of the drug in any way. Since 1984, no generic drug has been approved in the U.S. unless it has been shown to have the same rate and amount of active drug absorbed as the brand name.

A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.

Q. Are generics as safe as name brands?

A. As a group, generics have no proven side effects that are different from brand-names and are considered as safe. The FDA allows no drug on the market unless it is proven to meet their stringent safety, efficacy, and manufacturing standards. All generics are put through a rigorous multi-step approval process before they are considered brand equivalents. The FDA can also recall products if they do not meet production standards, and can even stop the manufacture of products until the manufacturing firm shows that it can make and test its drugs in a way that meets their high standards.

In reality, an estimated 50 percent of generic drug production is by brand-name firms or their subsidiaries. In some instances, brand-name firms sell both their original product and sell a generic version of it, too.

Q. Why do generic versions of a drug look different?

A. 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 ingredient. Colors, flavors, and certain other inactive ingredients may be different.

Q. How much money can I save with generic equivalents?

A. On the average, most generics are about half the price of the brand name, and some generics may cost up to 2/3 less than the brand-name version. There are several reasons for this, most notably, competitive pricing since there can be several different providers of generic equivalents.

Q. Why are generic drugs less expensive?

A. Generic drugs are less expensive because generic manufacturers do not have the same investment costs as compared to the original developer of a new drug. New drugs are developed under patent protection. The patent protects the investment – including research, development, marketing, and promotion – by giving the company the sole right to sell the drug while it is in effect. As patents near expiration, generic manufacturers can apply to the FDA to sell generic versions. The approval process does not require the generic drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Because those manufacturers do not have the same initial research and development (R&D) costs, they can sell their product at substantial discounts. Also, once generic drugs are approved, there is greater competition, which keeps the price down. Today, almost 90% of all human prescriptions are filled with generic drugs.



In addition, many brand name drugs have different prices for different markets. Brand name drugs intended for sale in Canada or Europe are often priced lower than the identical product sold in the U.S.A. In addition, special deals are often arranged between brand name manufacturers and not-for-profit organizations like hospitals. Some brand-name drugs sold to retail pharmacies can be several hundred times more expensive than the exact same drug sold to a not-for-profit hospital. This significant pricing disparity usually does not occur with generic drugs due to their lower costs.

Q. How can I make sure I can get a generic?

A. The laws governing generic substitution vary significantly from state to state. Only a licensed veterinarian, upon physical examination of your pet, can determine which drug may yield the optimal result for the condition being treated. However, unless the veterinarian writes "DAW" (dispense as written), "NS" (no substitutions), or "Brand Medically Necessary" on the prescription, you usually have the freedom to choose whether you want the brand name or the generic product. In some states, pharmacies must dispense the generic unless the veterinarian or pet owner requests no substitution. In other states, the pharmacy must receive authorization from both the veterinarian and the pet owner before a generic equivalent can be dispensed.

Q. Why aren't there generic forms of every medication?

A. In the United States, a company that develops a new drug can be granted a patent. Patents can be granted for many things, including the drug itself, a special way to manufacture the drug, a specific use for the drug, or the form of the drug (method of delivery). A company, then, can have more than one patent on the same drug. A patent gives the company exclusive rights to produce and sell the drug in that specific form for 20 years. This provides protection for the innovator who paid the initial costs (including research, development, and marketing expenses) to develop the new drug. Other companies cannot make exact duplicates. A company generally applies for a patent during the developmental stages of a drug, before it is ever marketed. In the U.S., there is often about 10-12 years between the time the patent is awarded and the drug is actually marketed. In most cases, then, the company only has the remaining patent time (about 8-10 years) to exclusively market the drug and earn its profits. Once the 20 years of the patent expires, regardless of how long the drug was actually on the market, other companies may produce and sell generic versions of the drug. It usually takes about three years for a generic drug to be developed and then approved by the FDA. However, recently approved legislation should enable the FDA to accelerate the approval process to encourage more generic drug availability.



The decision by a company to make a generic version of a drug is usually based on profitability. Even if the patent has expired on a drug, other companies may elect not to make a generic version. This is common for drugs that have limited indications for use, for example drugs that are used to treat rare conditions. Generic versions may also not be available if the manufacture and testing of the drug is very time consuming or financially unfeasible.

Q. How can I learn more about generics?

A. The Center for Veterinary Medicine (CVM) branch of the FDA offers a reference for generic equivalence called the "Green Book," which is available to all consumers on the internet at http://www.fda.gov/cvm/Green_Book/elecbook.html