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Generic versus brand name drugs ^[1]

Dear Alice,

I've been using name brand birth control pills for eight years and now my insurance company will only cover generic birth control pills. Do you know anything about the pros and cons of using generic pills as opposed to name brand pills? Are they as effective?

Thanks,
Confused

Answer

Dear Confused,

What's in a name? A brand name drug and its generic counterpart are chemically the same. They may have different names, colors, and shapes, but the United States Food and Drug Administration (FDA) requires generic drugs to be "clinically equivalent and interchangeable" to their brand name counterparts. And while there are some differences, generics don't really change the effectiveness of the drug's active ingredient — the biggest change is typically in the price (they're usually cheaper). Due to this, there are few differences between generic birth control pills and brand name — including their effectiveness. It's good to note though, not all brand name drugs have generic counterparts. Still curious about generic versus brand name? Read on!

Regardless of the type of drug, the FDA requires generics to be the same as the brand name in several respects: the active ingredients (that are responsible for the drug's effects), the dosage, and the way in which it's taken. This is called bioequivalency, meaning that the rate and amount of absorption into the bloodstream must match as closely as possible. Although the FDA sets a range of bioequivalency that a generic drug must meet, most generics closely align with the brand name counterpart. Similarly, the FDA requires that generic drugs have a comparable bioavailability (the amount of time the drug takes to be absorbed into the body under identical circumstances) to the brand name drug. A key exception to this rule is narrow therapeutic index (NTI) drugs. These are drugs where even slight differences in dosage or concentration in the bloodstream can impact the effectiveness or toxicity of the drug. However, the FDA has received no indication that there are significant clinical issues with brand name NTIs and their generic

counterparts. Overall, the FDA ensures that generic products match their brand name counterparts "with respect to identity, strength, quality, purity, and potency."

So, what's the big difference? Brand name drugs and the generics may differ in the coloring, shape, and name. These features are protected by the company that created the original product. Brand name drugs are usually protected under a 20-year patent, and after those 20 years are up, other companies are free to copy the drug and create generic versions. While the generic versions must have consistent bioequivalency and bioavailability, there may be some differences among the inactive ingredients, but those generally don't have any effect on the desired benefits of the medication. However, if a person has a negative reaction to a drug (brand name or generic), talking with a health care provider is advised to further investigate a possible intolerance or allergy to one of the inactive ingredients.

Another difference (one that may benefit you and your insurance company), is that generics typically cost less than brand name. Part of the rationale behind the patent is that brand name drugs cost more so the manufacturer has 20 years (the length of the patent) to recover those development costs before others start offering cheaper versions. You'll also be happy to know that generic drugs are regulated by the FDA and are required to meet the same safety and effectiveness guidelines as their brand name counterparts. The guidelines apply to the drug itself, as well as how it's manufactured, packaged, and tested. When it comes to birth control, most oral contraceptives (OC) for birth control have some form of generic alternatives. Although some manufacturers report slightly different levels of effectiveness (in general, OCs have a failure rate of less than one percent when taken consistently), there really aren't any significant differences. There may be an increase in side effects or higher risk of pregnancy, depending on how compliant you are with your birth control, but those risks aren't much different than if you were switching between two different brand name OCs.

So, in terms of effectiveness, there aren't significant down sides to taking a generic drug. In fact, there's no data to suggest that generic drugs are less effective. The only catch is that the specific drug you're currently using may not have a generic version at this time. Your health care provider can help you figure out your options. There may be a generic form of the birth control pill you've been using or your provider can advise you on switching to a different pill (or other birth control method) with a generic version available. You may also review your options with your insurance company — you can check out your insurance card for their customer service contact information to get more information on what options your plan will cover.

Here's hoping this information has got you covered on the differences between generic and brand name drugs.

Alice!

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