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**P**HARMACISTS AND PHYSICIANS reassure us: “Generic medications are exactly like brand.” The truth, however, is more complicated—especially when it comes to psychiatric medications. That goes doubly for medications such as the stimulant Concerta. Why? Because it uses sophisticated technology not easily replicated in a much cheaper generic.

Here is a brief Q&A to help you understand the issues with generic medications, particularly the FDA advisory regarding two inferior Concerta generics.

### **Q1: Wait, what? Generic medications aren't the same as brand?**

No, generics are not exactly the same as brand. They potentially differ in two key ways:

- **Unpredictable amount of the *active* ingredient (the actual medication)**

The key term to understand here is *bioequivalence*.

In the US, the FDA requires the *bioequivalence* of the generic product to be between 80 percent and 125 percent of that of the original, branded product. Therein lies the major problem. For many people with ADHD, precise dosing is critical. They find their “sweet spot” and can't go too much higher or lower without risking intolerable side effects—or insufficient positive effect.

For example, after careful experimentation with dosages, you realize that 50 mg of brand Medication X works best for you. Significantly less than 50 mg provides insufficient benefit. Much more than 50 mg creates an unacceptable degree of side effects.

Yet, when you pick up your generic version of Medication X at the drugstore, you have no idea what's in the bag, dosage-wise. Given the broad leeway for bioequivalence, the pill that you're expecting to contain 50 mg of Medication X might actually contain 40 mg or 70 mg.

- **Potentially different inactive ingredients (the dyes, binders, etc.)**

For example, the branded Ritalin and generic for Ritalin contain the same active ingredient: methylphenidate. Yes, the exact amount of methylphenidate in the generic product lies somewhere between 80 percent and 125 percent of your prescribed dose. But at least the active ingredient has the same chemical structure. Methylphenidate is methylphenidate.

When it comes to the *inactive* ingredients, it's another story. The brand and generic versions of a medication almost always contain different dyes, fill materials, flavoring, preservative, and binding (the substance that holds the pill together). Some people are allergic or highly sensitive to these substances. They might experience a negative reaction to a medication, but never having tried the brand, they won't know what exactly is creating the negative effect—the medication or the inactive ingredients.



# Exactly Like Brand?

A brief Q&A on generic medications, including the downgraded Concerta generics

BY GINA PERA





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What's more, pharmacies tend to purchase from multiple generic manufacturers. This can change month to month, without notice. The bottom line? These various generic versions of Medication X generic might differ significantly in both bioequivalence and inactive ingredients from the brand—and from each other.

### **Q2. Isn't there more than one category of generic medication?**

Great question! Yes, and we especially need to understand the two categories of generic medications before delving into the ongoing problem with Concerta generics:

- **True generic.** When the patent for a brand medication finally expires, generic manufacturers are free to produce their own version. The product is a generic in the commonly understood sense: a “bioequivalent” version of the brand medication, typically sold for a lower price.
- **Authorized generic.** Generics in name only, these products are the actual brand medications. They are simply marketed as a generic for price and insurance purposes.

This tends to happen when the brand is nearing its patent expiration. To forestall competition from a generic manufacturer, the brand manufacturer strikes a deal: The generic manufacturer can market its brand-manufactured pills as a generic if it delays making its own generics for a certain period of time.

The authorized generics usually present a win for consumers, because they are typically cheaper than brand. Moreover, some health insurance policies stipulate that prescriptions must be filled with a generic if one is available.

### **Q3: So what is the specific problem with Concerta generics?**

In a nutshell, there is no problem with the *authorized* Concerta generic. It is the brand sold as an authorized generic (You'll know it by the word “Alza” on the pill.) The problems came with the *true* generics, made by two different manufacturers, Mallinckrodt and Kremers-Urban (Kudco). Unfortunately, even though the FDA later downgraded these products as inferior, some pharmacies are still substituting them for brand. Unlawfully so.

Let's back up a bit. The authorized generic came first, in 2010. Nearing its expiring patent on Concerta, Janssen struck a deal. Watson (now called Actavis) would delay introducing its own generic to compete with Concerta. In return, Janssen would manufacture and allow Watson to sell its brand-name Concerta as an authorized generic. This deal lasts until December 2017.

The real complications in the Concerta generics story came about later, in 2012 and 2013, with the introduction of the true generics. That's when I started fielding some perplexing email.

Individuals who had taken Concerta successfully for years reported suddenly finding themselves struggling to get through the day. They (or their parents) didn't always “connect the dots” to the new Concerta generic that had replaced their regular Concerta. After all, their pharmacists and physicians were likely to assure them: “The generic is exactly like the brand!” Plus, life's variables keep changing. Puberty, extra stress, illness, and other factors can mean a medication can seem to have stopped working.

As the emails continued, I investigated the issue, including talking with the FDA about the potential, yet undiscovered, problems with these true generics. The technology that makes Concerta unique among other products that contain methylphenidate is the OROS technology. This is a laser-drilled capsule that releases the medication at a steady rate as it moves through the gut. The true generics did not utilize this proprietary technology. Essentially, they more resembled Ritalin LA.



Next, I opened a MedWatch complaint and publicized it on my blog. Kansas-based pediatrician Kristen Stuppy was also educating her blog readers on this topic. Gradually, a groundswell of consumer complaints to Federal Drug Administration's MedWatch program created an impact. The FDA reassessed how well these generics actually matched brand in performance. The conclusion? The bioequivalence was not close enough to brand. In November, 2014, the FDA downgraded the two generics, manufactured by Mallinckrodt and UCB/Kremers-Urban.

To be clear, these generics are not *unsafe*. In fact, some people actually prefer these generics. They simply don't release the methylphenidate into the blood stream in a similar pattern as with the brand Concerta. Thus, the bioequivalence is not sufficient to call them Concerta generics.

Unfortunately, two years later, some pharmacies are still substituting these downgraded generics for brand Concerta.

### Q 9. What does all of this mean to me or my loved one, as users of Concerta?

For now, it means that:

- By order of the FDA, pharmacies should not be substituting these inferior generics for Concerta.

- Always check your prescription before you pay for it. Otherwise, you might get stuck with an inferior generic product. The surefire way to know that you have brand or the authorized generic Concerta: Look for the word "Alza" on the pill.

- If your insurance pharmacy coverage stipulates that your prescriptions must be filled with available generics, you still cannot be forced to accept these downgraded generics.

- Your pharmacist should be able to order the Actavis authorized generic. If not, shop around for another pharmacist. Sometimes the independent pharmacies are more helpful.

- Of course, the brand Concerta is still available. The cost will vary, depending on your insurance coverage.

- For those who actually prefer one of these downgraded generics, each is still available. To be clear: There is nothing unsafe about these medications. They simply are not similar enough to Concerta to serve as the generics for it. 🚫

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- Treatment options
- Educational rights
- School and workplace challenges
- Tips on parenting, time management, legal issues, social skills, coaching, and more

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- Call the ADHD Helpline toll-free at **800-233-4050** Monday-Friday, 1 pm-5 pm ET for answers to your questions on ADHD (Se Habla Español)
- Attend free webcast series through *Ask the Expert*
- Connect with the ADHD community at [www.help4adhd.org/QA.aspx](http://www.help4adhd.org/QA.aspx)
- Search the web's only library dedicated to ADHD

The National Resource Center on ADHD is available to answer your questions and help you find the resources you need.



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