

Authorized Generic Concerta Update: 3/9/20

May 31, 2019 by Gina Pera [532 Comments](#) ([Edit](#))



**Concerta Update:
Recognizing and
obtaining the
authorized generic
(Psst! Brand
and authorized
generic say "Alza")**

ADHDRollerCoaster.org

Having trouble receiving the authorized generic Concerta—*again*? Well, you're in the right place.

I've been covering this issue for six years ([see list of posts](#)). Today I nailed down the latest details. But be warned: This is a rapidly changing scenario—and much depends on your particular insurance pharmacy benefit.

Update 3/9/20: Walgreen's and Possibly Other Stores

Beginning in June 2019, I attempted to gather more details by writing to and calling Patriot Pharmaceuticals. That was unfruitful. In fact, more than once I had to explain to the representative what is an authorized-generic.

Turns out, my reporting the problem here finally caught the company's attention. That's what I learned a few days ago, when returning a call from Patriot.

The call actually came last week but I was traveling and unable to follow up. In the meantime, a thoughtful reader, Zach, shared his shoe-leather reporting.

In speaking with the Patriot representative this morning (3/9/20), here is what I learned. It confirms and amplifies Zach's report. (Thanks again Zach!)

There Is An “Exception Process” at Walgreen’s, possibly Kroger and others

Walgreen’s corporate headquarters confirmed with Patriot that all Walgreen’s stores should be able to order the Concerta authorized generic for you. If you encounter resistance, ask that an *Exception Process* be ordered for you. Still trouble? Call Patriot at **215-325-7676**

Allegedly, Kroger has an Exception Process as well but I have not yet been able to confirm that with the corporate headquarters.

Other drugstores might be implementing such a policy. But no announcements have been made.

CVS has chosen not to participate.

Walgreen’s Is Your Best Bet Now—and Has Been Since This Issue Began, in 2014

I have no business interests with Walgreen’s. I can simply confirm that, since I first started to report on the Concerta generics issue (2014), Walgreen’s has been the most customer-focused chain. (Wegman’s, too, though Wegman’s stores are much smaller in number and regional.)

Walgreen’s must be taking a financial hit on this, so what’s the decent thing to do? Do your drugstore-sundry shopping at Walgreen’s, too.

Please note: I have not updated the rest of this post in light of this new information. If you remain confused about generic vs. authorized generic, however, you’ll find it useful to read the details—Gina

Quick Summary of this Post

In this post, you will

1. Learn to please stop asking for Actavis/Teva; you’ll be in for an unpleasant surprise.
2. Gain an overview of what’s been happening on this topic since June 2010.
3. Learn that the authorized generic is the brand; it’s simply sold as a generic.
4. Know that the authorized generic (brand marketed and sold at generic prices) is now distributed by Patriot Pharmaceuticals, a subsidiary of Janssen, Concerta’s manufacturer.
5. Be sure to read closely the section below under the heading: **How to Specify the Authorized Generic Concerta**
6. Find a bulleted summary of the main points at the end of this post—and a new infographic, because some readers are still having trouble understanding the details.

7. Consider getting the brand until the dust settles, if it's affordable, or trying one of the new methylphenidate medications (Ritalin, Daytrana, Aptensio XR, Metadate CD, Methylin, Quillivant XR, Jornay PM, Adhansia XR, Cotelpla, etc.)
8. If you participate in an ADHD-related forum or another type of group, please share the link to this blog post. I'm seeing folks repeat tidbits from this post but out of context and without updates—and therefore unhelpful.
9. **If you'd like to share a copy of this post with your prescriber or pharmacist—or anyone—click here to download [Authorized Generic Concerta Update](#).**

First, some background and context.

Tricky Transition Time Now

Even though the Concerta authorized generic is available, will your particular pharmacy agree to order it? Uncertain. Some pharmacies are more helpful than others, even within the same chain (e.g. Walgreen's, etc.).

Overall, pharmacies are increasingly choosing profits over customers. Regular generics tend to be more profitable than authorized generics. A reader commented on this post that, as an independent pharmacist, they *lose* \$100 on every authorized generic Concerta prescription.

Meanwhile, the clown car of new Concerta generics expands at a dizzying rate. We get two inferior generics downgraded one year and out pop several more the next! (See [Victory! Concerta Generics Downgraded](#))

To be clear: I receive no pharmaceutical funding of any type, and that includes from the makers/sellers of Concerta!

As I mentioned in the update above, Walgreen's seems to be the only chain officially committed to helping its customers get their prescriptions filled with the authorized generic of Concerta. There might soon be others, though.

Authorized Generic	True Generic
<ul style="list-style-type: none"> • Exactly same as the brand-name drug • Approved by the FDA as a NDA (New Drug Application) • Marketed, distributed, and sold and distributed as a generic product by a private label company • Identical to brand size, shape, smell, taste, active and inactive ingredients, etc. 	<ul style="list-style-type: none"> • "Bioequivalent" to brand-name drug in dosage, safety, and strength. • Produced and marketed under an Abbreviated New Drug Application (ANDA)

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Once Again: What Is An *Authorized* (or *Branded*) Generic?

A bit of background first.

Recently, Concerta users are starting to realize: The distributor of the *authorized* generic has changed again. From Watson to Actavis to Teva and now to Patriot Pharmaceuticals. Now, what should their prescriber specify? As always, I suggest *forgoing the distributor name*. It's too subject to change. I'll provide an alternate suggestion below.

To recap: Do you know the difference between "authorized" and regular generic medications? Many readers seem to remain confused.

I understand the confusion. Even many pharmacists and physicians can't tell you the difference. Moreover, many also insist that regular generic medications are "exactly the same" as brand. They are not. Consumer beware.

I've covered it before (again, [the roundup of blog posts](#)) but here are the basics:

1. Authorized generic (aka *branded generic*):

In fact, the *authorized generic is the brand*. It's only *marketed and sold* as a generic.

This typically happens when a brand drug patent nears expiration. Another company strikes a deal with the brand manufacturer: "We'll delay introducing our regular generic if you agree to let us sell your brand as a generic."

That's what happened with Concerta several years ago. The manufacturer, Janssen, agreed to let a company named Watson sell its brand Concerta as an authorized generic. As time went on, Watson became Actavis and Teva purchased Actavis.

Newsflash: Now Teva-Actavis has it's own generic

(but it's not the *authorized generic*).

If you are used to associating "Watson/Actavis/Teva"

with the authorized generic, please know that is outdated information.

In the past, the prescriber could specify on the prescription: "authorized generic Concerta/Watson, etc."—or simply OROS.

OROS is Concerta's patented extended-release technology, owned by a company called Alza and used by Janssen in making Concerta. (The **osmotic-controlled release oral delivery system**, OROS, takes the form of a rigid tablet with a semi-permeable outer membrane and one or more small laser-drilled holes in it.)

Since then, for a variety of reasons, it's gotten more challenging. Pharmacies are consolidating and are less "consumer-oriented." Some of the new generics use other osmotic technology. As a result, some pharmacists mistake "osmotic technology" for the proprietary OROS from Alza.

2. True generic:

This is what most of us regard as a generic medication. It's a cheaper alternative to a brand medication. It is made by a different company, not the brand's manufacturer.

Even though it is often claimed to be "exactly the same" as the brand, it is not. Unfortunately, pharmacy insurance benefits increasingly force consumers to accept these generics or pay a very high cost for the brand.

For more details, read [Consumer Q&A on Concerta Generics](#)

New Concerta Generics From At Least *Nine* Companies

Over the last two years, the situation has grown even more confusing. At least seven (SEVEN!) companies released Concerta generics since July 2017:

1. Manufacturer: **ACTAVIS LABS FL**
Approval date: March 21, 2018
Strength(s): 54MG [AB]
2. Manufacturer: **ACTAVIS LABS FL**
Approval date: March 22, 2018
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB]
NOTE: Actavis used to be the distributor for the *authorized* generic Concerta; now it has its own generic.
3. Manufacturer: **ALVOGEN PINE BROOK**
Approval date: November 30, 2018
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB], 54MG [AB]
4. Manufacturer: **AMNEAL PHARMS**
Approval date: February 1, 2018
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB], 54MG [AB]
5. Manufacturer: **ANDOR PHARMS**
Approval date: April 24, 2019
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB], 54MG [AB]
6. Manufacturer: **ANI PHARMS INC**
Approval date: July 14, 2017
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB], 54MG [AB]
7. Manufacturer: **MYLAN**
Approval date: October 21, 2016
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB], 54MG [AB]
8. Manufacturer: **OSMOTICA**
Approval date: July 28, 2017
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB], 54MG [AB]
9. Manufacturer: **PAR PHARM**
Approval date: July 15, 2019
Strength(s): 36MG [AB], 54MG [AB]
10. Manufacturer: **ASCENT PHARMS INC**
Approval date: September 3, 2019
Strength(s): 18MG [AB], 27MG [AB], 36MG [AB], 54MG [AB]

NOTE: The Ascent generic (distributed by Camber) uses a barrell-shaped pill. It seems designed to fool consumers/physicians/pharmacists that this generic uses OROS. It does not.



Note red arrows for two points of identifying the authorized generic Concerta: NDC code (last two numbers will differ by dosage) and distributor (Patriot Pharmaceuticals)

Who Sells the Authorized Generic Concerta Now?

Now the new seller is Patriot Pharmaceuticals, as shown on the label above. Patriot is a subsidiary of Concerta manufacturer Janssen. The corporate office tells me there is no planned termination date for this arrangement. Meaning, it should continue until it doesn't.

In the old days (about 4 years ago), the companies made public these marketing deals. Consumers knew when the deal would take effect, when it was set to expire, when it expired or was re-negotiated—and how long *that* would last. After Teva purchased Actavis in 2016, however, I found impossible to extract any details from the company.

Since that time, Teva has removed the authorized generic from its website. Actavis/Teva now sells its own generic. The marketing deal to distribute the authorized generic has gone to Patriot Pharmaceuticals.

"One Word Stands Out - Authorized"

click above for more info

**Patriot
Pharmaceuticals Is The New *Distributor***

In fact, Patriot Pharmaceuticals is a subsidiary of Concerta maker Janssen. It sells *only* authorized generics. As its website tagline says: *One Word Stands Out—Authorized.* (See blurry screen capture above.)

Just in case visitors also don't understand the term *authorized generic*, the website spells it out:

Patriot Pharmaceutical Generics are authorized for sale to trade customers by the NDA holder of the innovator product. [Note: *NDA* stands for New Drug Application. It the vehicle through which a company proposes that the FDA approve a new pharmaceutical for sale and marketing in the U.S.. Not a new generic of an existing brand, a new pharmaceutical altogether.]

The entire Patriot family of products is made by the same manufacturers that are approved in the NDAs of the innovator products.

The same qualities you relied on in the innovator pharmaceutical products during their branded lifecycle are now available in Patriot's authorized generic line of products. [A *branded life cycle* means "before the patent expires".]

You'll find Patriot's handy Q&A here: [About Authorized Generics](#)



How to Specify the Authorized Generic Concerta

As promised, here are the updated details, including the unique identifying number, a list of distributors, and the name of the drug. I accessed this information from the [U.S. National Library of Medicine "Daily Med" website](#).

1. Name:

Methylphenidate HCl Extended-release tablets

NOTE! You cannot rely just on the name; all the Concerta generics (including the authorized generic) are named this!

2. You Will Need The Identifying NDC Code:

Each FDA-approved medication (brand or any kind of generic) is assigned a code, the NDC (National Drug Code). Here are the numbers for Concerta's authorized generic (the last two numbers vary by dosage):

- 10147-0685-1 – 18 mg
- 10147-0688-1 – 27 mg
- 10147-0686-1 – 36 mg
- 10147-0687-1 – 54 mg

My advice is: Ask your prescriber to specify the NDC number.

Note: If your pharmacy says that number is not coming up in their database, they might instead find the 11-digit billing code. For example, the 36 mg replaces one hyphen with a zero. That is, **NDC 10147-0686-1** has a billing code of **NDC 10147068601**. For the full details, click here: [NDC 10147-0686-1 METHYLPHENIDATE HYDROCHLORIDE](#).

If your insurer or pharmacy needs more information, click here to download my highlighted copy of the [Concerta Authorized Generic Label Insert](#).

3. Distributors:

What if—despite taking the steps above—your pharmacy benefit company still says, “But we can’t find that”? or “It’s on back order”?

It might be that store or chain simply will not order it for you, under any circumstances.

To check, call the Patriot Pharmaceuticals customer service at **215-325-7676**

4. How Should The Prescription Read *Exactly*?

There are no ironclad answers here. Your prescriber might have a preference. But the pharmacy might, too. If possible, try to get a straight answer from the pharmacy *before* speaking with your physician.

In the best of all possible worlds, the script need only contain the name of the drug! But in the case of Concerta generics, they are ALL called *Methylphenidate Hydrochloride (HCl)* Extended-release tablets. That makes it critical to establish *which* one.

To be crystal clear, the prescription should read something like this (for example, for the 36 mg dose):

Methylphenidate HCl Extended-release tablets, 36 mg, NDC 10147-0686-1 ONLY

The “ONLY” at the end indicates, “do not substitute with another generic.”

Note: Some readers report that their pill bottles exclude the HCl (which stands for hydrochloride). If the pills say “Alza,” don’t worry about it.

5. Pay Attention to the “No Substitutions” Box

Tricky Bit: Your prescriber must pay attention to the prescription pad checkbox that indicates “no substitutions” or “dispense as written” (it varies by state).

If that is checked, pharmacists typically take that to mean, “do not substitute a generic.” That means you might get *brand*—at brand prices—or one in the clown car of new generics.

But what happens when the prescriber checks that box AND specifies a generic but uses the name of the brand (Concerta) instead of Methylphenidate HCl, etc.?

Well, anything can happen! That’s why I think it makes sense to use my suggestion above. *But again, ask your pharmacist first!*

If you use a home-delivery pharmacy, consider attaching a note pointing out your request. Maybe print and include this blog post.

And yes, you can get stimulants via home-delivery pharmacy if you have that benefit. It is NOT illegal!

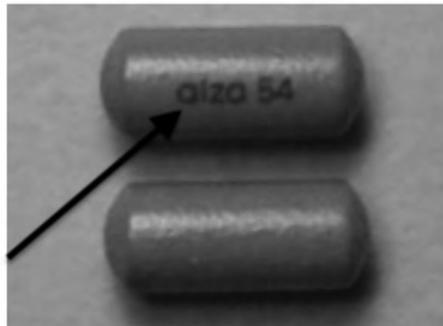
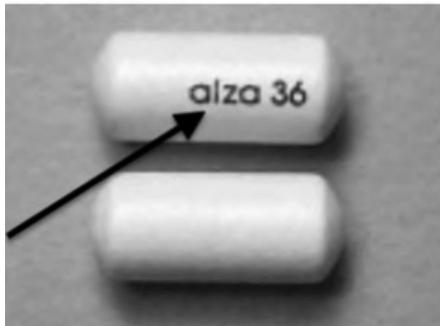
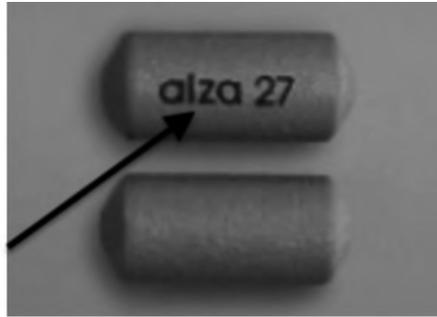
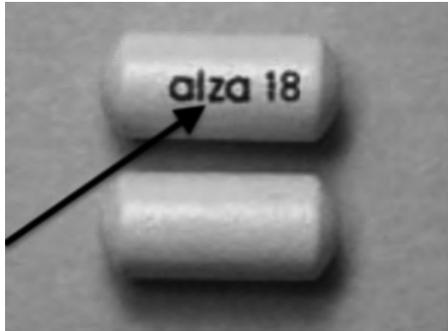
One problem with local pharmacies is that they often cannot fill a 30-day prescription for stimulants of any kind; the home-delivery pharmacies have larger supplies and quicker access.

See [Tip: Home Delivery of Prescribed Stimulant Medications](#)

6. What Should The Pills Look Like? Look for *alza*

NOTE: Look before you pay!

The pills should look exactly the same as the brand—because they *are* the brand. It’s easy. Just look for the word *Alza* on the pill. If it doesn’t say *alza*, it’s not Concerta brand or authorized generic.



Caution: Camber's capsule only superficially resembles Alza's OROS. It lacks the actual patented technology.



True OROS technology would say "alza"



7. Must the Pharmacy Fill the Prescription As Written?

Sorry, I cannot answer that, despite solid efforts to learn. I suspect it's going to vary by state. If you are in the know, please leave a comment.

Here is an article in *U.S. Pharmacist* that might help: [Generic-Substitution Laws](#).

8. What Should The Label Look Like?

Before you leave the pharmacy or open a home-delivery bottle, look for the label. It should say "Patriot Pharmaceuticals."

Do not pay for the prescription until you check the label and the pills themselves. If you want Concerta brand/authorized-generic, they should look like the pills in the photo above.



This is the new label for Concerta’s authorized generic. It looks the same for all dosages. Look for “Patriot.”

If All Else Fails, Purchase the Brand

Some folks cannot wait until the last minute and roll the dice. They need continuing dependability.

If that’s you, check your pharmacy benefit’s cost for brand Concerta. Or check out savings from GoodRx.

But *Do* Investigate Home-Delivery Pharmacy Benefit

Does your insurance pharmacy benefit include a home-delivery pharmacy? If so, consider using it!

If you use a home-delivery pharmacy, you might end up paying less for the brand Concerta than for generic at your storefront drugstore each month. It just depends on your policy. If you have CVS Caremark as your home-delivery pharmacy, you might be out of luck for the authorized generic. But if you must purchase brand, home-delivery should offer a cost-savings.

Yes, this is legal! Read more here: [Tip: Home Delivery of Prescribed Stimulant Medications](#)

Summary

I know this is a lot to take in! (It was a lot to research and attempt to write about clearly, too—not to mention field reader questions.)

I hope these quick points clarify things for you. If not, leave a question in the comments section. Readers who have followed my suggestions *precisely* seem to have a higher success rate.

—There are two types of generics, *authorized* (the brand marketed as a generic) and *true* (what we normally think of as generics).

—Over the years, we could purchase the brand Concerta as an *authorized generic*, via distributors Watson (then Actavis, then sold to Teva).

—But now, Actavis/Teva *has it's own true generic*, and so do six other manufacturers! **Bottom line:** Please stop referring to the branded/authorized-generic as “Actavis-Teva.” Unless you want a big surprise!

—None of the Concerta true generics utilizes Alza’s patented OROS delivery mechanism.

Many argue that without that delivery system, it cannot be a reasonable substitute for brand Concerta. My blog readers played a critical role in asking the FDA to reassess the first two Concerta generics (the FDA ended up downgrading them as not being close enough to Concerta). Here is my report on that issue: [Consumer Q&A on Generic Concerta](#)

—Some of the true generics utilize *osmotic* technology. But that is *not* the same as Alza’s patented OROS (osmotic-controlled release oral delivery system). Many pharmacists do not know this! You might need to tell them!

Summary of Tips and Strategies:

—The name for ALL the Concerta generics (the authorized-branded generic or the regular generics) is *Methylphenidate HCl Extended-release tablets*. Therefore, *to specify the authorized generic, you’ll need to add something else*—for example, the NDC number. This is a unique number-identifier for each medication (and even each dosage strength). See the instructions above.

—If your pharmacy says they can’t find Concerta’s authorized generic, try another pharmacy—either within the same chain or a different chain. Or even a different person at the store. Some are more willing to help than others. If you have a Walgreen’s, you might want to make it your first stop. If your efforts run dry, call Patriot Pharmaceuticals for help in identifying a local pharmacy that might fill your prescription with the authorized generic for Concerta. **215-325-7676**

—Home delivery pharmacies have bigger inventory and greater access; that might be your best bet. NO, it’s not illegal to ship Schedule II substances, including stimulant medications. For more info, [check this link](#).

—If you have a choice of local pharmacies, independently owned stores typically are more service-oriented than the big chains.

But keep in mind: Pharmacies are reimbursed at a rate no higher than the cheapest generic. That means fulfilling these prescriptions can lose the pharmacy money. This can hit independents

hard, big chain pharmacies less so. So, please don't hold it against the pharmacy if they cannot help.

—So-called true generics are NOT “exactly the same as brand”—no matter what any medical professional or pharmacist tells you.

—ALWAYS ALWAYS ALWAYS check the bottle before you pay for it at the pharmacy register. If you pay only to discover that you have a generic that you do not want, you are probably stuck.

Please Consider Filing an FDA MedWatch Complaint

—If you have tried one of these true generics and found it significantly inferior to brand/authorized-generic Concerta, please consider filing a MedWatch complaint with the FDA. You can download a PDF or file directly online.

- More information at this link: [Reporting Serious Problems to the FDA.](#)
- [Click here to go directly to the form.](#)

HOW TO SPECIFY AUTHORIZED-GENERIC CONCERTA

1 FORGET "ACTAVIS"

Actavis was never the brand. It was only the distributor. Actavis (owned by Teva) no longer has the license to distribute the brand as generic (the "authorized generic"). Moreover, it now has its own generic, which does not use the Alza OROS proprietary technology.

2 JANSSEN IS THE MANUFACTURER OF BRAND AND "AUTHORIZED GENERIC"

Janssen is the manufacturer of Concerta and always has been; it is also the manufacturer of the authorized generic (because it IS the brand, marketed as a generic). Recently, a Janssen subsidiary, Patriot Pharmaceuticals, became the distributor of the authorized generic. But don't ask for "Patriot." Use the NDC numbers below.

3 USE THESE NDC NUMBERS

Each medication has a unique identifier in the U.S. National Drug Code Directory (NDC code). These are numbers for Concerta's authorized generic:

- NDC 10147-0685-1 - 18 mg
- NDC 10147-0688-1 - 27 mg
- NDC10147-0686-1 - 36 mg
- NDC10147-0687-1 - 54 mg

4 LOOK FOR "ALZA" ON THE CAPSULE

Concerta (brand or authorized generic) relies upon a unique proprietary delivery system (Alza's OROS capsules), and none of the other generics uses that. Hence they are much cheaper.

5 CHECK THE BOTTLE BEFORE PAYING

You cannot return medication after you have opened it. So, ask the pharmacy clerk to show you the pills

The first version of this post appeared 6/19/19

Thanks for reading! Please leave a comment below. It's easy.

**I answer all questions as quickly as possible.
Gina Pera**

Share with your friends!