



When you are Prescribed an Off-Label Medicine:

What You Need to Know

Q: What should you do if your healthcare provider prescribes a medicine for you and you find out that the medicine is not normally used to treat your condition?

A: Ask your doctor. It's possible you've been prescribed a medicine for an **"off-label"** use. **Off-label** prescribing is when a physician gives you a drug that the U.S. Food and Drug Administration (FDA) has approved to treat a condition that is different than yours. This practice is legal and common. In fact, one out of every five prescriptions written today is for **off-label** use. Under Federal law, the FDA must approve all new prescription drugs using evidence that the medicine is safe and effective for a particular condition. This allows a drug maker to market a drug for the use the FDA agreed it works. While a company is not allowed to market an approved drug for other purposes, the law does let physicians prescribe the medication to treat a condition for which it is not approved.

Q: Are off-label drugs safe?

A: This is a good question to ask your doctor. Most doctors only prescribe **off-label** when they are confident the medicine will work well for treating a condition. **Off-label** drugs can help patients when approved treatments aren't working or when patients have rare conditions that don't have approved treatments.

Heart medicines, antipsychotics, and antibiotics are commonly prescribed **off-label**. Beta blockers, for example, were first approved for treating high blood pressure but have since been found to be good for treating heart failure and migraines. Some medicines designed to treat depression also are used to treat chronic pain.

All drugs carry risks, however. Treatment decisions involve weighing possible risks against possible benefits. Sometimes the risks outweigh the benefits. When it comes to **off-label** drugs, sometimes there isn't enough reliable evidence to make informed decisions.

Research funded by the Agency for Healthcare Research and Quality (AHRQ), shows that some newer antipsychotic drugs developed to treat schizophrenia and bipolar disorders are prescribed to millions of Americans who suffer from depression, dementia, and other conditions. But there's no evidence that these drugs work to treat them.

That is a problem because **another AHRQ study** found that adults who took certain antipsychotic drugs had a higher risk of sudden death from heart disease than patients who did not take them.

This research should help doctors and patients weigh the risks and benefits of these drugs before prescribing them for depression or for other **off-label** uses.

Advice for Consumers and Caregivers:

Talk with your doctor if you have concerns about any medicine or treatment, particularly if it may be **off-label**. Here are several questions to ask:

- Is this the approved use of the medicine? You may not know if the use is **off-label**. This question can help you start the conversation with your doctor about your medicines.
- Is the **off-label** use of this drug likely to be more effective than one approved to treat my illness? This is important because the **off-label** drug may not be as well tested for your condition.
- What evidence shows that this **off-label** drug can treat my condition?
- What are the risks and benefits of **off-label** treatment with this drug?
- Will my health insurance cover **off-label** treatment with this drug?

Source: ([Navigating the Health Care System](#); Advice Column from Dr. Carolyn Clancy, AHRQ; April 21, 2009)

For additional questions to ask about your medicines, visit: www.talkaboutrx.org.

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