



Understanding Off-Label Use of Drugs and Medical Devices

What does “off-label” mean?

The Food and Drug Administration (FDA) approves all drugs and medical devices before they can be sold to the public. Each drug or device is approved for a specific use or purpose. But often, it can be used to treat other conditions as well.

When doctors prescribe something for a purpose not approved by the FDA, it is called “off-label” use.

How are drugs and devices used off-label?

Off-label use can take several forms.

- A drug may be used to treat a disease not listed on the package insert. For example, a doctor may prescribe an anti-depressant to treat headaches.
- A doctor may give you a different dose from that listed on the package insert.
- A device approved for one kind of surgery may be used in another. For example, surgeons may use a device to stabilize a patient’s spine, even though it was approved for use in the leg bones.

How common is off-label use?

Off-label use is very common, and it seems to be growing. In some cases, it is the standard treatment for a given condition. It also plays a large role in advancing drug therapy and medical care.

Studies have shown that most hospital patients have received at least one drug off-label. And for some drugs, off-label use accounts for most of the sales.

How risky is off-label use?

There is no direct link between off-label use and medical risk. Risk depends on:

- how different the off-label use is from the standard treatment of your condition
- evidence to support the off-label use.

When off-label use has been well studied and is accepted practice, there is no increased risk. In such cases, not offering off-label use to patients may be improper.

Will my doctor tell me if I’m using a drug or device off-label?

Doctors do not routinely mention off-label use. It is so common that in many cases it does not warrant a discussion. If you have questions or concerns about off-label use, be sure to ask your doctor.

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