

Off-Label Prescribing Explained

Why your doctor may recommend meds that aren't FDA-approved for your condition

Once a prescription drug is approved for at least one indication, physicians can prescribe it for other disorders or symptoms for which they believe it would be effective. This practice is called off-label prescribing.

Drug manufacturers are not permitted to market off-label uses of pharmaceuticals. However, doctors are legally permitted to recommend medications for reasons other than those approved by the FDA.

At least one in five prescriptions is written for an off-label use, according to a study published in the *Archives of Internal Medicine*. The researchers found that off-label use was most common for heart and allergy drugs and least common for those used to treat high blood pressure (hypertension) and diabetes.

The most common off-label use (84 percent) was for gabapentin (Neurontin), which is approved only for epileptic seizures and for pain that persists after a case of shingles. It is often prescribed for a wide range of

conditions, including bipolar disorder, diabetic neuropathy and restless legs syndrome.


You can learn whether your prescription is for an approved indication or an off-label use by asking

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your doctor, reading the information on the package insert or checking the FDA website (www.fda.gov).

There may be good scientific evidence to support an off-label use, but that use may never be formally studied. It's often not worth a drug company's expense to launch clinical trials to gain approval for a valid new indication when a drug is already successful for another purpose.

Even without strong scientific evidence, doctors often have sound reasons for prescribing a drug off-la-

bel. In fact, the practice is considered by many to be an essential component of the "art of medicine." 

Questions for Your Doctor

If you do find out that your prescription is for an off-label use, it's usually not cause for alarm. But it is a good idea to consider asking your doctor the following questions:

- Is there an FDA-approved drug for my condition?
- If so, why are you prescribing this drug rather than one that is FDA-approved for my condition?
- Is there evidence from clinical trials to show that this drug is more effective or safer than the drugs currently approved to treat my condition?
- Is the drug approved to treat conditions that are related to, or similar to, my symptoms? For instance, it may make sense to prescribe an asthma drug to someone who has breathing problems that are due to a different lung disease.

Weight Gain (*continued from page 2*) calories a day), set a goal for yourself of consuming 250 fewer calories and burning 250 calories more each day.

HELP FROM THE EXPERTS

Losing weight, particularly if you need to shed more than a few pounds, can be challenging. If you don't want to go it alone, ask your doctor to refer you to a registered dietitian. A few sessions can put you on the path to significant, sustained weight loss. A dietitian can also help design a weight-loss program that keeps in mind your other health problems, such as diabetes or heart disease.

Or, you might want to consider a commercial weight-loss program,

like Weight Watchers or Jenny Craig. Beware of expensive programs that promise results that sound too good to be true.

START SLOWLY

While you are in the hospital, you'll meet with a physical therapist who will teach you gentle range-of-motion and muscle-strengthening exercises. Continuing to do the exercises for several weeks after you're discharged will aid in your recovery.

For knee replacement and hip replacement surgery alike, it takes about four weeks to reach 80 percent recovery. Full recovery may take a year or longer for knee replacement surgery

and about six months for hip replacement surgery.

It's not necessary to fully recover before starting a more intensive exercise regimen for weight loss, but you do need your doctor's okay. In general, low-impact exercises, such as swimming, bicycling and walking, are best. Choose activities that you enjoy so you'll stay motivated. Don't forget to work on strength training and flexibility as well.

Finally, don't overdo it. Gradual improvement is the goal. Aim for at least 150 minutes per week (30 minutes a day, 5 days a week) of moderate-intensity exercise (rating a 5 or a 6 in intensity on a scale of 10). 