

Medicine Safety and You: Understanding ‘Side Effects’

Medicines can help you get well, avoid disease, or feel better. However, all medicines, both prescription and over-the-counter, have benefits *and* risks. Benefits are helpful effects, such as reducing pain, shrinking a tumor, or lowering blood cholesterol. Risks are the possibilities that a medicine could cause an unwanted or unexpected negative effect. Most of these effects are minor, such as temporary dry mouth or sleepiness, but some can be serious, such as an increased risk of bleeding or heart attack.

When scientists study a new medicine in a clinical trial, they use the term “adverse events” to describe any observed problems in people taking the medicine. Such “adverse events” may or may not have been caused by the medicine, but it’s important to record these events and try to find out if there is a connection. A problem known to be associated with a particular medicine is often called an “adverse effect” or an “adverse reaction” by those who specialize in medicine safety. The common term for such problems is “side effects,” and they are a key concern for patients and physicians.

Any medicine, no matter how safe and effective, has the potential to cause side effects. The benefits of any medicine must be weighed against its possible risks. Government regulators review evidence about the benefits and risks of a new medicine in clinical study patients before approving it for use by the public; doctors and patients make their decisions based on patients’ health needs and preferences.

Your medicine decisions should be made in a partnership between you and your doctor or other health care professionals. Another important consideration in these decisions is the risk posed by not treating the underlying disease. The challenge is to determine whether the risk of side effects is outweighed by a medicine’s potential benefits in treating or preventing disease. By learning more about medicine safety, benefits, and side effects, you can participate in more informed health care decisions with your health care team.

Will a medicine have side effects?

The perfect medicine would target only the health problem and have no other effects on the body. Such a perfect medicine doesn’t exist, however. All medicines have the potential to produce effects beside their intended ones. The chance of experiencing side effects varies widely, depending on the medicine, how it is used, what other medicines a person is taking, and an individual’s characteristics (such as age, weight, other diseases, and risk factors).

With your doctor, explore the answers to these questions about any new medicine:

What is the chance that side effects will occur?

Your doctor can’t predict for certain whether you will experience a particular side effect or not, but he or she can inform you of what to look out for, and how to respond if such effects occur.

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Some medicines seldom cause side effects, while others (such as some cancer drugs) can produce such effects in almost every user. Some side effects are common with a particular medicine, while others are rare. Some adverse events are serious in nature and others are nonserious.

What are the possible consequences?

You may have noticed that some medicines come with warning labels about rare or uncommon, but serious, adverse events. In general, these merit concern because the consequences pose a serious risk of life-threatening or permanent harm. Even the chance of a rare serious adverse event occurring in *someone* increases if large numbers of people take that medicine over time; however, the benefits provided by the medicine may still be worth the risk, depending on factors including the seriousness of the underlying disease.

Medicines must undergo extensive testing before being approved for sale, and manufacturers and government regulatory agencies continue to monitor for adverse events (which may or may not be related to the medicine) after approval. Medicines that demonstrate the potential to cause serious side effects are only approved if the known benefits of the medicine for the condition it is intended to treat outweigh the apparent risks. For this reason, minor side effects (those that cause no lasting problems and often go away on their own) are much more common than serious ones. Pharmaceutical companies and regulatory agencies have set up systems to gather and respond quickly to reports of serious and unexpected adverse events in patients taking approved medicines. For more information, see the post-approval segment of the Medicine Safety Timeline at www.pfizer.com/medicinesafety.

Side effects also vary in how bothersome they are. For example, a medicine may cause great discomfort, like itching or headache, but without causing any permanent harm. Depending on the benefits offered by the medicine, many patients and doctors may accept only side effects that are neither serious nor very bothersome. (Note: Some effects that themselves might not be deemed serious, such as drowsiness, can cause serious personal safety risks if the person operates a car or machinery. Be sure to follow all label and package warnings about activities while using a medicine.)

Is there anything I can do to reduce the risk of side effects?

Definitely. Start by asking your doctor or pharmacist about the potential for side effects with any new medicine, whether prescription or nonprescription.

Know your medicines. Learn the name (generic and brand) of all medicines you take, and what condition they are intended to treat. Keep an up-to-date list of all your medicines (prescription, nonprescription, and dietary and herbal supplements), including dosage, and bring it to all medical appointments. If you research your medicines on the Internet, double-check what you learn with your doctor or pharmacist, because not every Web site is reliable. Major pharmaceutical companies have informational Web sites for patients regarding the medicines they produce, and these may be a good place to start. Government organizations that regulate medicines, like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), are other reliable sources.



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Read the label and follow directions. Once your prescription is filled, take the medicine exactly as prescribed. If you forget to take it or intentionally skip a dose, ask the doctor or pharmacist what to do (don't automatically double up the next dose). And if you have trouble affording your medicine, don't split pills to save money. (With some medicines, taking partial doses can be harmful.) Instead, ask about more affordable alternatives, or available programs to help people get access to treatments they need.

If you read something on the label or package insert of your prescription medicine that alarms or confuses you, don't just ignore it or avoid taking the medicine! Talk to your doctor about your concerns. Your doctor prescribed the medicine to give you a particular set of benefits, and you and your doctor should discuss whether the benefit/risk profile of this medicine is appropriate for you.

Know your health care history and share it with your health care professional. If you have had any allergies, sensitivities, or side effects with medicine in the past, say so. Make sure your doctor knows about all current and past health conditions and risk factors.

Avoid interactions. Some side effects may result from taking a medicine with a specific food or beverage (such as grapefruit juice) or another medicine or health-related product (including vitamins and herbal supplements), which may cause harmful interactions. Note and follow any warnings on the label or packaging about interactions, and ask the doctor or pharmacist what else you should know (such as whether or not the medicine should be taken with food, or whether it's safe to take it with other medicines you already take).

Minimize side effects if possible. Side effects with some medicines may be reduced by taking them with meals or at a certain time of day or through other strategies. Again, follow the label or packaging, and ask your doctor or pharmacist for tips.

What action should I take if I experience a possible side effect?

Keep track of a medicine's effects on body and mind. Ask your doctor what to expect from your medicine—how soon you should experience improvement, what side effects may occur, and whether you will need any follow-up testing or monitoring. Know what to do if you experience side effects and when to alert your doctor. If in doubt about whether to alert your doctor, it is better to do so. It's a good idea to write down any changes or possible side effects you experience.

Not every change you may experience when taking a medicine is necessarily a side effect of that medicine, but it is still important to contact your health care professional. Sensations or symptoms may result from an underlying health problem or an interaction between two medicines you are taking. Your doctor must consider when the problem started, other possible causes for it, and the known side effects profile of the medicine itself. The doctor's recommendations might include discontinuing medicine for your condition, changing to another medicine, or changing the dosage.



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The appropriate choice will depend on how important the benefits of the medicine are to your health, and how serious or bothersome the side effects are.

Fill out the following with your physician or other health care provider for your prescribed medicine(s). If you take more than three medicines, print out extra copies of this page.

My prescription medicines:

	Medicine 1	Medicine 2	Medicine 3
Brand name	_____	_____	_____
Generic name	_____	_____	_____
Dosage (the amount of medicine to be taken at one time, e.g., 10 milligrams once per day)			
Benefits (what this medicine is for)			
Possible side effects to be aware of			
If side effects occur, take this action			

