

...About Tips Against Tampering

Are you taking steps to protect your medications—and yourself?

To protect consumers, over-the-counter (OTC) or nonprescription medicines now are packaged so that signs of tampering can be noticed more easily. But the protective system doesn't end when you buy the medicine and bring it home. You are part of the system and have a responsibility to detect any damage or problems that could point to tampering.

The tips in this booklet will help you detect signs of tampering. For some products, these tips will help you only if you know how the product normally looks. But if you have any concerns or questions about a product, always ask the pharmacist.

How can you protect yourself?

You can look, observe, check, and consider...very carefully.

Follow these tips on a regular basis when you buy medicines:

- Consider the dosage form (for example, capsules, syrup), the type of packaging, and whether the tamper-evident features used, if any, will cause you any problems in opening the container.
- Look very carefully at the outer packaging of the drug product before you buy it. After you buy it, also check the inner packaging as soon as possible.

- Do not buy the product if the protective packaging as described on the label is broken or looks like it has been tampered with in any way. If you notice signs of tampering after you buy the medicine, return it to the store; and be sure to tell someone in charge about the problem.
- Do not take medicines that show even the smallest signs of tampering or do not seem quite right (for example, a liquid that looks cloudy or discolored or pills that smell or look funny).
- Never take medicines in the dark or in poor lighting. Look at the label and examine the medicine itself every time you take a dose.

What should you look for?

Inspect packaging, liquids, tablets, capsules, tubes, and jars. When it comes to your medicines, it pays to be a skillful sleuth. Know what to look for and make a complete inspection. Use this checklist for your investigation.

FOR PACKAGING:

- Are there bits of paper or glue on the rim of the container that look like it once had a bottle seal?
- Does the cotton plug or filler in the bottle seem to have been taken out and put back?
- Are there breaks, cracks, or holes in the outer wrapping or protective cover or seal?

- Does the outer covering look like it has been unwrapped, replaced, or tampered with in some other way?
- Does the bottle look like it is too full or not full enough?
- Is the cap on tight?
- Does a plastic or other shrink band (tight-fitting wrap) around the top of the bottle look stretched or moved like it has been rolled down and then put back into place? Is the seal missing? Has the band been cut and retaped?
- Is the bottom of the bottle intact? Are there prick marks, cracks, or other marks on it?
- Is the information—including expiration date and lot number—on the container the same as that on the outer wrapping or box?

FOR LIQUIDS:

- Is the liquid the color and thickness that it usually is?
- Are there particles—small pieces—in the bottom of the bottle or floating in the solution? (Note that for some liquids called suspensions, floating particles are normal).
- Is a normally clear liquid cloudy?



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- Does the liquid have a strange or different odor, such as bleach, acid, gasoline, or other pungent or sharp odor?
- Do eye drops have a protective seal? All eye drops must be sealed when they are made to keep them germ-free. Do not use if there is any sign of a broken or removed seal.

FOR TABLETS:

- Do they look different than they should look? Is the color different? Do they have unusual spots? If they normally are shiny and smooth, are some dull and rough?
- Do the tablets have a strange or different odor or taste?
- Are the tablets all the same size and thickness?
- If there is printing on the tablets, do they all have the same imprint? Is the imprint missing from some?

FOR CAPSULES:

- Are they cracked or dented?
- Do they have their normal shiny appearance, or are some dull or have fingerprints on them as though they have been handled?
- If there is printing on the capsules, do they all have the same imprint? Is the imprint missing from some? Do the imprints all line up the same way?

- Are they all the same size and color?
- Are the capsules all the same length?
- Does the filling in all the capsules look the same?
- Do they have an unexpected or unusual odor?

FOR TUBES AND JARS (OINTMENTS, CREAMS, PASTES, ETC.):

- Is the tube properly sealed? Check the bottom as well as the top of a tube, especially if it is a metal tube crimped up from the bottom like a tube of toothpaste. It should be sealed firmly.
- Are ointments and creams smooth and non-gritty? Have they separated?

Don't overlook or tolerate tampering!

Use these tips to protect yourself and your medicine.

If you take the tips against tampering to heart, you can make sure the medicines you and your family take are as safe and effective as possible. Look for signs of tampering before buying a medicine and each time you take a dose.

Have a question? Ask your pharmacist.

Whenever you suspect tampering, have your pharmacist look at the product. He or she will know

how a product or package is supposed to look and feel. If there are serious concerns or problems, ask your pharmacist to report them to the Food and Drug Administration at www.fda.gov/medwatch/index.html or other appropriate authorities.

A tamper-resistant package is required either to be unique so that it cannot be copied easily, or to have a barrier or indicator (that has as an identifying characteristic, such as a pattern, picture, or logo) that will be easily noticed if it is broken. For two-piece, unsealed, hard gelatin capsules, two tamper-evident features are required. Improved packaging also includes the use of special wrappers, seals, or caps on the outer and/or inner containers, or sealing each dose in its own pouch.

