



THE FAMILY PHARMACIST

A QUICK READ FOR YOUR OTC NEED!

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THE TRUTH ABOUT EXPIRATION DATES

Have you ever started to open or use a tube of antibiotic ointment, pain reliever medicine, or bottle of eye drops only to see that the date on the package was expired? You ask yourself, *hmm...should I use it or not? Will it hurt me if I do?* I've been asked this question many times and even pharmacists want to know the answer to this question. So let's look at what the experts say. You may be surprised at what studies have found.

According to an article published in 2012 in the journal, *Archives of Internal Medicine*, "Expired medications have not necessarily lost potency, since the expiration date is only an assurance that the labeled potency will last **at least** until that time." The Food and Drug Administration states that drug expiration dates reflect the time period during which the product is known to remain stable, which means it retains its "strength, quality, and purity" when it is stored according to its labeled storage conditions. In other words, when a manufacturer submits an application to the FDA the time period used for the expiration date on the label is the length of time they studied the drug (and know for sure) that it is what they say it is. It could be stable and effective (the ability to produce the desired result) much longer, they just don't know because they haven't studied it beyond that time. However, ongoing independent studies show that many medications retain their strength and efficacy years after their labeled expiration dates.

The study in the journal mentioned above was based on eight drug products (containing 15 different active ingredients) that were discovered in a retail pharmacy. The medications were in their original, unopened containers and all had expired 28 to 40 years prior to being analyzed! Twelve of the ingredients tested were still present in concentrations at least 90% of the labeled amounts. This is impressive because the US Food and Drug Administration (FDA) permits "reasonable variation" such that some medications market-

ed in the United States (at the time these drugs were made) could contain 90% to 110% of the amount of the active ingredient claimed on the label. So most of the analyzed, expired medications still met the minimum acceptable potency of the day.

I want to be careful to explain that such a study shouldn't allow us to take license and use expired medications indiscriminately. The drugs mentioned in the study above were found in their original, unopened containers. Apparently, there was no (or minimal) exposure to light and moisture. Also, all of the drugs analyzed were tablets or capsules, no liquids, creams, etc.

There are other things to think about too. Sometimes you want to strictly follow the labeled expiration date. For example, eye drops that are clearly labeled on the container to be sterile when purchased should not be used after the expiration date. Why not? Well, "sterile" means there is a guarantee that the product is free, not only of bacteria, but viruses and other living organisms. In addition, sterile usually means that the product has been subjected to a temperature and pressure sufficient to eliminate other microscopic contaminants that can cause problems. Using the product after it has expired eliminates the guarantee that it is safe and free of contaminants. Once the product seal is broken on an eye drop and used for the first time take care not to contaminate it.

Regarding other drug products that have no guarantee of sterility, notice that the FDA definition in the second paragraph includes the words "quality and purity." A drug could have retained its full efficacy but be of questionable "quality," that is, contaminated with particulate matter or losing its original color, and so on. This is especially true of liquids, creams, ointments, sprays, etc.

Most medicines get an expiration date ranging from one to five years from the day of **manufacture**. But after examining

40 different products currently on local drug store shelves, it appears that expiration dates on OTC medications can range anywhere from only nine months to two years beyond the day you **purchase it**. Not a lot of time. And there isn't much variation from one type of drug to the next or from one therapeutic category of medicine to another. The table below shows the average expiration time in months found for various categories of over-the-counter products on pharmacy shelves.

Product Type	Average Months To Expiration
Eye Products	21 months
Oral Liquid Medicines	16 months
Creams/Ointments	18 months
Tablets/Capsules	20 months

So, what is the practical implication of this information? The FDA allows manufacturers to arbitrarily set the expiration date without really knowing the long term stability of the drug. If manufacturers were to study drug stability longer and extend the expiration date it could save consumers tons of money. Like food, untold amounts of medication are discarded unused because they are past the expiration date. This would also make the preparation and storage of home medicine kits for use in an emergency or natural disaster more practical. And with regard to that bottle of pain reliever that's slightly out of date, you can rest assured that it's not going to hurt you and it will still relieve your pain. At least until you can buy an in-date supply.

References on file

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