

Maybe it's time to think twice about taking acetaminophen (tylenol®)

written by Alan Kadish | February 2, 2023



Over-the-counter medications may not be as safe as one assumes.

Most of us assume, generally falsely that if a medication is over the counter it's safe. Obviously, the FDA has allowed the manufacturer to market the substance in your grocery store. You're always aware of the following long-on-the-shelf products, such as Tylenol, generic acetaminophen, Nyquil, Dayquil, or Excedrin. The commonality is their contents of acetaminophen the active pain reliever ingredient.

Did you know that [~90% of the pediatric population](#) has used acetaminophen ? In Europe, the same medication is known as [paracetamol](#). And to add to your knowledge of how prevalent the use is, according to the [Consumer Healthcare Products Association](#), ~ 52 million consumers which is approximately 23 percent of U.S. adults in the U.S. use products containing Tylenol each week.

Recalls and Dose Limits:

As a consumer did you know that Tylenol began marketing in 1955. In 2009 the FDA started requiring guidelines for adding overdose information to products with acetaminophen. Then in 2011 the FDA confirmed the link between acetaminophen and liver damage and added a black box warning. This is the **strongest** label warning for prescription medication, This was then followed up by limiting the amount of acetaminophen in all drug products to 325mg per dose. The story continues and in 2013 the FDA sent a safety warning that acetaminophen can cause rare but serious skin reactions.

Not unlike other medications acetaminophen has had its recalls. After lots of reports in early 2008 of strange smells from their product, McNeil recalled many Tylenol brands because a chemical for treating wood, [2,4,6-tribromoanisole \(TBA\)](#), made it into the medicine, causing nausea, vomiting and diarrhea. It was not until 2009, after an FDA warning letter that the recall took place. In 2011, the recall was expanded recalling several more lots of the medication. To be clear this recall involved tens of thousands of Tylenol products ultimately having Johnson & Johnson close a manufacturing plant. Because of the egregious infractions, the FDA started supervising quality control measures at three plants. Then in 2012, McNeil recalled nearly 600,000 bottles of [infant Tylenol](#) for faulty dosing systems that could result in babies receiving too little or too much medicine.

Legal:

Perhaps there should be more to this story as a new set of 87 [lawsuits](#) in 7 states against such chains as Costco, CVS Health, Rite Aid, Safeway, Target, Walgreens and Walmart are in play. The suits are based on women who when pregnant

were taking acetaminophen and birthed an offspring that is experiencing either ADHD or autism symptoms. And speaking of lawyers who are focusing on the acetaminophen suits, they reportedly spent over [\\$2.1 million](#) in mass tort advertising by November 2022. This represents the third largest advertising outlay for any mass tort action.

For anyone interested in joining these ongoing suits the general criteria is simple: You took Tylenol®, Excedrin®, DayQuil®, or NyQuil® while pregnant. Tylenol®, acetaminophen, or paracetamol must have been taken before and during the **third** trimester of pregnancy, together with your child having a diagnosis of one of the following, Autism, ASD, Asperger's, PDD-NOS, Childhood Disintegrative Disorder, or ADHD. If your child is currently under 18 years old, the mother must be the legal guardian pursuing the claim on the injured party's behalf. If your child is older than 18, but younger than 29, the mother must be willing to assist with the case to qualify.

As a note, not all products containing acetaminophen are stated that way on the label. Look for synonyms that include: APAP, AC, Acetaminoph, Acetaminop, Acetamin, Acetam, and Paracetamol. This practice is almost gone due the efforts of the FDA and the National Council for Prescription Drug Programs (NCPDP) to standardize acetaminophen exclusively.

Drugs and Pregnancy

All physicians are taught that because of the high potential of adverse events during pregnancy, including malformations, any medications should be only used **if necessary** and only choose the least potentially dangerous, as appropriate. The system of classifying medications for use during pregnancy started in 1979 by the FDA with a range from category A to X, with A being considered safe and X absolutely contraindicated. Acetaminophen had been in category B. Only

a few medications were ever recognized as really safe category A, such as thyroid medications.

The newest update took place in 2015 using narratives, with three subdivisions, Pregnancy, Lactation and Female and Male Reproductive potential. For an in-depth discussion of the history and the current system see : [FDA Pregnancy Risk Information: An Update](#)

Scientific Studies:

20 peer-reviewed studies have found an association between the development of brain disorders and the use of the over-the-counter analgesic drug, which was licensed in the mid-1950s and is the most widely used physician-recommended pain reliever worldwide.

A notable study in the [American Journal of Epidemiology](#), titled Prenatal Exposure to Acetaminophen and Risk for Attention Deficit Hyperactivity Disorder and Autistic Spectrum Disorder: A Systematic Review, Meta-Analysis, and Meta-Regression Analysis of Cohort Studies " attributes a 30 percent increase in the risk of ADHD and a 20% increase in the relative risk of autism spectrum disorder (ASD) if a mother took high (keywords) amounts of acetaminophen during her pregnancy. This study included seven retrospective cohorts which included 132,738 mother-child pairs, with follow-up periods ranging from 3 to 11 years. Keep in perspective that this evaluation is based on observational information.

In another publication in 2022, [Maternal use of acetaminophen during pregnancy and neurobehavioral problems in offspring at 3 years: A prospective cohort study](#), of the >1000 women who used acetaminophen during pregnancy they saw an association between the medications use and attention and sleep problems in the offspring.

In a more recent follow-up study, "[Prenatal and postnatal exposure to acetaminophen in relation to autism spectrum and attention-deficit and hyperactivity symptoms in childhood: Meta-analysis in six European population-based cohorts](#)" their evaluation builds on prior work. They focused on 6 European groups of 73,881 mother-child pairs and the findings were again present, "results indicated that children prenatally exposed to acetaminophen were 19% and 21% more likely to subsequently have borderline or clinical Autism Spectrum Conditions (ASC) and Attention-Deficit/Hyperactivity Disorder (ADHD) symptoms "

As with many drugs, there is an ongoing debate about their safety and no lack of manipulation of statistics when it comes to commerce and big money. In a May 2022 literature review, "[Paracetamol \(acetaminophen\) use in infants and children was never shown to be safe for neurodevelopment: a systematic review with citation tracking](#)" the researchers did a dive into the literature and found 218 publications that claimed acetaminophen as safe. Now for the rest of the story... 52 of the papers actually had experiments testing for safety... but...the time to assess if the drug was safe was a median time of 48 hrs. Nowhere near enough to evaluate any of the underlying neurodevelopmental issues that are of concern. The only good news from this review, "paracetamol does not induce acute liver damage in babies or children when used as directed."

Some Chemistry:

What would you say if to date there are competing theories as to how acetaminophen works ? There are 4 common concepts including controlling fever and pain by blocking an enzyme called cyclooxygenase (COX-1), interacting with the endocannabinoid system or altering signals from the neurotransmitter serotonin or perhaps it inhibits neurotransmitter receptors in the brain, including N-methyl-

D-aspartate and substance P which are our way to feel pain.

To understand another of the underlying issues with the “safe” use of acetaminophen, it’s known to reduce [glutathione](#) in our bodies, even with low doses. Glutathione is our major antioxidant in the body and not a chemical we want to suppress, typically. It’s essential to keep our body in balance, with free radicals.

Did you know that according to [DrugWatch](#) “acetaminophen is the leading cause of liver failure in the U.S. and it’s one of the most common causes of poisoning, accounting for “100,000 calls to poison centers, roughly 60,000 emergency-room visits and hundreds of deaths each year in the U.S.”

Take Aways:

Check your medication labels for acetaminophen content

Fevers are nature’s way to gear up our immune system they may be uncomfortable but a good way for our bodies to fight infection

Don’t combine alcohol and acetaminophen as it reduces your anti-oxidant levels

For high fevers, consult with your physician/pediatrician

Warm baths can be helpful to stabilize a fever

Always use the least amount of medication necessary