

# Tylenol

## The safety of acetaminophen during pregnancy or breastfeeding

The information provided below is for readers based in the United States of America. Readers outside of the United States of America should seek the information from local sources.

### **THIS MEDICATION MAY CAUSE HARM TO YOUR BABY:**

Acetaminophen can be used in any trimester of pregnancy, with only short-term use at small doses recommended. Human studies that have looked at the safety of acetaminophen during pregnancy indicate that taking acetaminophen during pregnancy has a low risk of harming the baby, but overuse can increase the risk of negative side effects in babies. Acetaminophen is considered compatible with breastfeeding when used in regular doses.

#### **What is acetaminophen?**

Acetaminophen is a medication that is taken to relieve pain symptoms. Acetaminophen is currently available as a generic or brand name (for example, Tylenol) medication. In 2011, the maximum dose and time between doses of acetaminophen were increased in order to decrease accidental acetaminophen overdoses. Acetaminophen is available in caplets, extended-release caplets, capsule, solution for injection, oral solution, rectal suppository, suspension, syrup, chewable tablet, disintegrating tablet, and liquid tablets and is taken every 4 to 6 hours. It is available over-the-counter and by prescription from your doctor.

#### **What is acetaminophen used to treat?**

Acetaminophen is used to relieve pain and fever in children and adults.

#### **How does acetaminophen work?**

Acetaminophen works by interfering with pain signaling in the brain and reducing fever by inhibiting heat regulation in the hypothalamus (part of the brain).

#### **If I am taking acetaminophen, can it harm my baby?**

Although regular use of acetaminophen is not recommended during pregnancy, acetaminophen is considered safe during pregnancy if used short-term and in small doses. Recent studies suggest overuse of acetaminophen during pregnancy may be associated with negative events. There has been no proven association between maternal acetaminophen use and birth defects or miscarriages in babies exposed to the medication before birth.

### **Evidence from animal studies with acetaminophen:**

There are no animal studies evaluating intravenous acetaminophen, but studies in pregnant rats exposed to oral acetaminophen at doses similar to maximum human doses report an increased risk of toxicity to the baby, skeletal defects, and liver/kidney toxicity. When given to pregnant rats and rabbits at much larger doses than the maximum recommended human dose, acetaminophen was found to cause reduced birth weight, delayed bone development, and a higher rate of stillbirths (death of the offspring after 20 weeks of pregnancy). It was not associated with a higher rate of birth defects.

### **Evidence for the risks of acetaminophen in human babies:**

- Overdose or high maternal doses

Persistent high maternal doses or overdoses of acetaminophen have been associated with fetal liver and kidney toxicity, fetal distress, and miscarriage in case reports. In a British study that examined acetaminophen overdoses in pregnant women, 4% of newborns exposed to higher doses of acetaminophen developed birth defects such as heart defects, defects of the penis, cleft palate, eye defects, and spina bifida. However, this birth defect rate was similar to the normal rate of birth defects in women not exposed to acetaminophen, so acetaminophen was ultimately not associated with an increased risk of birth defects.

- Risk of birth defects

A study in Michigan found a 4.6% rate of birth defects with first trimester acetaminophen exposure, which did not show an association between acetaminophen and birth defects. A study in Denmark noted a 10.9% risk of birth defects (heart defects, hip dislocation, eye defects) with acetaminophen exposure 30 days before conception through the first trimester of pregnancy; however, the range of birth defects reported suggested that there is no proven relationship between acetaminophen and birth defects. The Collaborative Perinatal Project suggested that exposure to acetaminophen during pregnancy may increase the risk of hip dislocation and clubfoot in babies. One laboratory study reported an increased risk of abdominal defects in babies with certain genetic defects that prevent

acetaminophen metabolism and breakdown in the body. The Baltimore-Washington Infant Study found an increased risk of 2 types of heart defects in babies exposed to acetaminophen 3 months before to 3 months after conception. In several Danish studies, there was a proposed association between undescended testicles in male infants and acetaminophen exposure in early to mid-pregnancy. Other studies including the National Birth Defects Prevention Study and the Boston Collaborative Drug Surveillance Program have found no increase in the risk of birth defects with acetaminophen exposure during pregnancy. The National Birth Defects Prevention Study found that the use of acetaminophen for first trimester maternal infection and fever may *reduce* the risk of select birth defects.

- Risk of neurobehavioral development issues

Acetaminophen exposure in utero has not been proven to negatively affect child intelligence or growth; however, the Norwegian Mother and Child Cohort Study found that greater than 28 days of exposure to prenatal acetaminophen increased the risk of poor motor development, communication difficulties, and behavioral issues in 3-year-old children. The Danish National Birth Cohort study reported an association between acetaminophen exposure and parent-reported hyperactivity symptoms, with more frequent dosing associated with greater risk. Further studies have identified a potential association between prenatal acetaminophen exposure in utero and autism development. The 2018 Mother and child, Asthma and allergy (SELMA) study found an association between language delays in children age 30 months and in utero acetaminophen exposure during the first trimester. Greater acetaminophen use increased the risk of this adverse effect.

- Risk of asthma

Acetaminophen exposure has not been conclusively linked to the development of asthma; first and third trimester use of acetaminophen may *decrease* the risk of asthma development in babies. The Peer Education in Pregnancy Study found that maternal use of acetaminophen during the second or third trimesters of pregnancy significantly increased the risk of wheezing in children by 1 year of age. A 2009 study in 1500 women and their children found no significant increase in the risk of asthma with acetaminophen exposure; first and third trimester exposure to acetaminophen decreased the risk of asthma. In one cohort study comparing 35,816 children exposed to acetaminophen during pregnancy to 27,836 children whose mothers never used acetaminophen during pregnancy, children exposed to acetaminophen had a greater risk of developing asthma. Other studies in the United States, Denmark, United Kingdom, Spain, and Norway report an association between acetaminophen use during

pregnancy and asthma development in children, but many of these studies have failed to account for other factors that may have influenced the results including the use of multiple medications and maternal respiratory tract infections. In the Avon Longitudinal Study of Parents and Children (ALSPAC) cohort study, certain genetic differences in babies were found to mediate the effects of prenatal acetaminophen exposure and development of asthma.

- Risk of attention deficit hyperactivity disorder (ADHD)

A study in 7 to 11-year-old children exposed to acetaminophen in utero found an increased risk of ADHD. In a Danish National cohort study, children exposed to acetaminophen at any point during pregnancy had a 37% higher risk of hyperkinetic disorders, a 29% higher risk of being prescribed ADHD medications, and a 13% higher risk of having ADHD behaviors at 7 years of age. The risk of ADHD-related behaviors increased with maternal use of acetaminophen for more than one trimester of pregnancy and with higher doses of acetaminophen. Analysis of data from the Avon Longitudinal Study of Parents and Children (ALSPAC) cohort found an increased risk of behavioral problems with maternal prenatal acetaminophen use, but not with postnatal use of acetaminophen. A 2017 analysis of data from the Norwegian Mother and Child Cohort Study found an association between long-term (>29 days) maternal acetaminophen use during pregnancy and the risk of ADHD. The Society for Fetal-Maternal Medicine has concluded that evidence in human studies suggesting a possible link between acetaminophen exposure during pregnancy and neurobehavioral development problems in babies is inconclusive.

**Bottom line:** Short-term use of small doses of acetaminophen should be safe during pregnancy. The risk of birth defects and other mother/baby adverse events have not been proven to be associated with prenatal acetaminophen use. It is important to use acetaminophen carefully during pregnancy in order to avoid any potential problems.

### **If I am taking acetaminophen and become pregnant, what should I do?**

If you are taking acetaminophen and become pregnant, you should contact your doctor immediately. Your doctor will determine if your medication is medically necessary, or if it should be discontinued until after the birth of your baby.

### **If I am taking acetaminophen, can I safely breastfeed my baby?**

The American Academy of Pediatrics and the World Health Organization considers oral acetaminophen compatible with breastfeeding. The use of intravenous acetaminophen requires

consideration of the benefits of breastfeeding, the maternal benefit of acetaminophen therapy, and potential risks to the baby from exposure to this medication. Only small amounts of acetaminophen are present in breastmilk. There has been one case report of a nursing infant who developed a rash with acetaminophen exposure through breastmilk.

**Bottom line:** Breastfeeding should be safe to continue while on oral acetaminophen. Only one case report of infant rash has been reported with acetaminophen exposure in breastmilk.

### **If I am taking acetaminophen, will it be more difficult to get pregnant?**

Animal studies in mice and rats have reported decreases in the number of live births, abnormal sperm and sperm development in males, and decreased fertility in females with acetaminophen exposure more than two times the maximum recommended human doses.

### **If I am taking acetaminophen, what should I know?**

Short-term use of small doses of acetaminophen should be safe to use throughout pregnancy. The risk of birth defects and other adverse events have not been proven to be associated with prenatal acetaminophen use. It is important to use acetaminophen judiciously during pregnancy in order to avoid any potential problems.

The American Academy of Pediatrics and the World Health Organization consider acetaminophen compatible with breastfeeding.

### **If I am taking any medication, what should I know?**

This report provides a summary of available information about the use of acetaminophen during pregnancy and breastfeeding. Content is from the product label unless otherwise indicated.

You may find Pregistry's expert reports about the individual medications used to treat pain [here](#), our report about pain [here](#), and our report about fever [here](#). Additional information can also be found in the resources below.

For more information about **acetaminophen** during and after pregnancy, contact <http://www.womenshealth.gov/> (800-994-9662 [TDD: 888-220-5446]) or check the following link.

U.S. Food and Drug Administration: [Acetaminophen Prescribing Information](#)

**Last Updated: 04-02-2020**

## General information

It is very common for women to worry about having a miscarriage or giving birth to a child with a birth defect while they are pregnant. Many decisions that women make about their health during pregnancy are made with these concerns in mind.

For many women these concerns are very real. As many as 1 in 5 pregnancies end in a miscarriage, and 1 in 33 babies are born with a birth defect. These rates are considered the background population risk, which means they do not take into consideration anything about the health of the mom, the medications she is taking, or the family history of the mom or the baby's dad. A number of different things can increase these risks, including taking certain medications during pregnancy.

It is known that most medications, including over-the-counter medications, taken during pregnancy do get passed on to the baby. Fortunately, most medicines are not harmful to the baby and can be safely taken during pregnancy. But there are some that are known to be harmful to a baby's normal development and growth, especially when they are taken during certain times of the pregnancy. Because of this, it is important to talk with your doctor or midwife about any medications you are taking, ideally before you even try to get pregnant.

If a doctor other than the one caring for your pregnancy recommends that you start a new medicine while you are pregnant, it is important that you let them know you are pregnant.

If you do need to take a new medication while pregnant, it is important to discuss the possible risks the medicine may pose on your pregnancy with your doctor or midwife. They can help you understand the benefits and the risks of taking the medicine.

Ultimately, the decision to start, stop, or change medications during pregnancy is up to you to make, along with input from your doctor or midwife. If you do take medications during pregnancy, be sure to keep track of all the medications you are taking.