Advil

The safety of ibuprofen 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 CAN CAUSE HARM TO YOUR BABY:

Nonsteroidal anti-inflammatory drugs should be avoided during the first and third trimesters since these medications may be harmful to the developing baby. It is important to weigh the risks versus benefits of taking nonsteroidal anti-inflammatory drugs while nursing an infant.

What is ibuprofen?

Ibuprofen is a nonsteroidal anti-inflammatory (NSAID) medication, used to relieve pain, fever, and inflammation. Ibuprofen is available as Advil™ or Motrin™. Ibuprofen is taken three to four times daily (maximum dosage recommended) by capsule, tablet, solution, or injection. Doses are given based on weight in children. Ibuprofen is available over-the-counter or by prescription.

What is ibuprofen used to treat?

Ibuprofen is used to manage symptoms of mild to moderate pain and/or fever associated with conditions such as osteoarthritis, dental pain, backaches, common cold or flu, muscle or joint pain, sore throat, menstrual cramps, migraines, and rheumatoid arthritis in children, adolescents, and/or adults.

What is pain and inflammation?

Pain is an uncomfortable feeling that can be produced from an injury. Injury stimulates pain receptors throughout the body that then communicate with the spinal cord and brain. Pain intensity and duration can vary among individuals as well as the tolerability of pain. Inflammation is caused by the release of chemicals in the body that stimulate heat and swelling. Inflammation can occur due to an acute injury or it can be a chronic condition in the body.

How does ibuprofen work?

Ibuprofen works by inhibiting enzymes in the body that are responsible for producing chemicals called *prostaglandins* that cause pain and inflammation. Nonsteroidal anti-inflammatory drugs are most effective when taken every 4 hours (pain relief). These medications have a quick onset of action and the duration of pain relief lasts a few hours, requiring frequent dosing for pain relief.

If I am taking ibuprofen, can it harm my baby?

The FDA has stated that the use of prescription nonsteroidal anti-inflammatory drugs during the first half of pregnancy may increase the risk of miscarriage. In the third trimester of pregnancy, nonsteroidal anti-inflammatory drugs should be avoided due to an increased risk of complications in the baby such as premature closure or non-closure of the *ductus arteriosus* (an artery that should remain open to bypass the undeveloped lungs in utero, but close after birth to allow for oxygenation of the blood), infection/inflammation of the intestines, low amniotic fluid levels, kidney injury, and bleeding in the brain. Ibuprofen can also prolong pregnancy and prevent labor. Ibuprofen may be recommended during pregnancy in select women with rheumatoid arthritis or migraine; however, other medications may be recommended over ibuprofen, particularly during early and late pregnancy. Ibuprofen has warnings for increased risk of gastrointestinal bleeding or stroke in select patients, and the medication is contraindicated in patients with prior open heart surgery.

Evidence:

Animal studies

Oral doses of ibuprofen given at 0.912 times the recommended human dose resulted in maternal toxicity and heart defects in the developing baby. Animals given ibuprofen were reported to have delayed birth, increased stillbirths, and increased postimplantation loss. Other animal studies using pain relieving oral doses of ibuprofen in pregnant rats and rabbits found no increase in the risk of birth defects. Rectal administration of ibuprofen in pregnant rats and rabbits was associated with decreased birth weight and increased maternal deaths.

Birth Defects

Studies have found no decrease in infant survival and no increase in the risk of birth defects including heart defects with first trimester use of ibuprofen. A study based on the Danish Birth Registry found no association between ibuprofen exposure during pregnancy and birth defects. The Boston Collaborative Drug Surveillance Program found no increase in birth defects with first trimester exposure to ibuprofen. A Swedish study found no increase in heart defects with ibuprofen use in early pregnancy.

The National Birth Defects Prevention Study concluded that the use of nonsteroidal anti-inflammatory drug use during early pregnancy is not a major risk factor for birth defects in babies; however, the study did report small increases in oral cleft, brain and spinal cord, limb, and eye defects with exposure to naproxen, aspirin, and ibuprofen during early pregnancy. A German study compared women who took ibuprofen during the first trimester to women who did not take ibuprofen during early pregnancy, finding no increase in risk of major birth defects. A Danish study found no association between exposure to ibuprofen during pregnancy and undescended testicles in male babies. A Danish study reported an increased risk of shortened anogenital distance (distance from anus to genitals) in male babies, not female babies, exposed to NSAIDs and/or acetaminophen during the first 28 weeks of pregnancy. A Danish and Norwegian study of exposure to ibuprofen in pregnancy found no association with the development of cerebral palsy. A review of Michigan Medicaid participants whose newborns were exposed to ibuprofen during the first trimester of pregnancy reported a 4.5% risk of major birth defects, which is similar to the risk of birth defects in the general population. Case-control studies suggest ibuprofen use in early pregnancy may be associated with an increased risk of abdominal wall defects and oral/facial defects. Nonsteroidal anti-inflammatory drugs other than ibuprofen may increase the risk of heart defects when used in the first trimester of pregnancy. The Baltimore Washington Infant Study suggested a possible association between ibuprofen exposure in pregnancy and heart defects. The Swedish Medical Birth Registry suggested an association between nonsteroidal anti-inflammatory drug use in pregnancy and mild heart defects; however no specific nonsteroidal anti-inflammatory drug was specified.

Miscarriage

Exposure to NSAIDs close to the time of conception has been associated with miscarriage. In 2015, the FDA released a statement on pain medications in pregnancy, and discussed the risk of miscarriage with use of presciprtion NSAIDs in early pregnancy. A study in 1055 pregnant women found that more than 1 week of prenatal nonsteroidal anti-inflammatory drug or aspirin use was associated with an increased risk of miscarriage. Israeli and Quebec studies have found condlicting evidence in regards to risk of miscarriage with ibuprofen use during early pregnancy. A Danish study evaluated women who suffered miscarriages to determine if nonsteroidal anti-inflammatory drug use during pregnancy contributed to the miscarriage. While there was no increase in the risk of birth defects or premature delivery, the use of these medications was associated with an increased risk of miscarriage. A review of pregnant women in Northern California (n=1097) who were exposed to NSAIDs in early pregnancy, particularly around the time of conception, were found to have an increased risk of miscarriage. There was a greater risk of early miscarriage, and women with lower body mass index had a greater risk of

miscarriage than women with higher body mass index.

Prematurity and pregnancy loss

A recent study in pregnant women in Quebec who were exposed to nonsteroidal anti-inflammatory drugs in late pregnancy (within 3 months of delivery) found an increase in premature delivery. In the Quebec Pregnancy Registry, any non-aspirin nonsteroidal anti-inflammatory drug use during pregnancy was associated with an increased risk of pregnancy loss. A study in 4500 Israeli women exposed to nonsteroidal anti-inflammatory drugs during pregnancy found no increase in risk of pregnancy loss. The Right From the Start Study found no increase in the risk of pregnancy loss in pregnant women exposed to over-the-counter nonsteroidal anti-inflamm
atory drugs during the first trimester of pregnancy. A study based on the Danish Birth Registry found an association between ibuprofen exposure during the first trimester of pregnancy and an increased risk of pregnancy loss. A study in 53 women who reported using ibuprofen around the time of conception found an increased risk of pregnancy loss.

Other potential complications

A Norwegian study in over 6,000 pairs of women and children exposed to nonsteroidal anti-inflammatory drugs during pregnancy found no increase in the risk of birth defects; however, second and third trimester use of these medications was associated with an increased risk of low birth weight, child asthma, and maternal bleeding. A Norwegian study compared 1,080 sibling babies who were exposed to ibuprofen during the first trimester with 26,824 sibling babies without exposure to ibuprofen, finding an association between ibuprofen and low birth weight. The Norwegian Mother and Child Cohort Study found no evidence that ibuprofen use during pregnancy can negatively affect neurological development in children later in life. In Project Viva, early pregnancy use of nonsteroidal anti-inflammatory drugs for fever relief was associated with an increased risk of early childhood asthma. A study in 399 women who developed preeclampsia during pregnancy and who were treated with nonsteroidal anti-inflammatory drugs found no increased risk of persistent postpartum high blood pressure. Another study analyzed babies born with *persistent pulmonary hypertension of the newborn* (PPHN, defined as high blood pressure in the arteries of the lungs) and maternal use of nonsteroidal anti-inflammatory drugs during pregnancy. The study found no association between PPHN and the use of non-aspirin nonsteroidal anti-inflammatory drugs anytime during pregnancy or use of ibuprofen during the third trimester of pregnancy. An increased risk of *pulmonary hypertension* or high blood pressure in the arteries of the lungs has been reported in infants exposed to diclofenac. Ketorolac has been associated with PPHN in newborns as well as poor blood flow in the baby and inhibition of

uterine contractions that support the recommendation to avoid ketorolac during labor and delivery. The use of nonsteroidal anti-inflammatory drugs such as ibuprofen has been associated with premature closure or non-closure of the *ductus arteriosus* (an artery that should remain open to bypass the undeveloped lungs in utero, but close after birth to allow for oxygenation of the blood), infection/inflammation of the intestines, and bleeding in the brain. To avoid premature closure of the ductus arteriosus, ibuprofen should not be used starting at 30 weeks gestation. If considering the use of ibuprofen before 30 weeks gestation, it is important to weigh the risk versus benefits of using this medication while pregnant.

Bottom line: Nonsteroidal anti-inflammatory drugs should be avoided during early pregnancy or close to labor and delivery. When taken during pregnancy, nonsteroidal anti-inflammatory drugs have been associated with complications in newborns.

If I am taking ibuprofen and become pregnant, what should I do?

If you are taking a nonsteroidal anti-inflammatory agent and become pregnant, you should contact your doctor immediately. While many studies have failed to show an increased risk of birth defects with nonsteroidal anti-inflammatory drugs, there is an increased risk of miscarriage as well as other potential complications including PPHN and childhood asthma. Your doctor may decide to stop your medication until after your delivery to ensure the safety of your baby.

If I am taking ibuprofen, can I safely breastfeed my baby?

There is very little data available on the effects of nonsteroidal anti-inflammatory drugs on the breastfed baby. The evidence that is available suggests that these medications do not cause harm to the baby, and adverse events have not been reported. Breastfeeding is thought to be compatible with ibuprofen use by the American Academy of Pediatrics and the World Health Organization. It is estimated that nursing infants receive 0.6% to 0.9% of a mother's dose of ibuprofen. Ibuprofen is a preferred pain reliever and anti-inflammatory medication for use while nursing due to the presence of low levels of the medication in breast milk. If nonsteroidal anti-inflammatory drugs are needed while breastfeeding, they should be used sparingly. Ibuprofen should be avoided in women who are nursing and have platelet dysfunction. It is important to weigh the risks versus benefits before using ibuprofen while nursing an infant.

Bottom line: It is important to weigh the risks versus benefits of continuing nonsteroidal anti-inflammatory drug therapy while nursing an infant.

If I am taking ibuprofen, will it be more difficult to get pregnant?

Nonsteroidal anti-inflammatory drugs have been associated with decreased fertility and early pregnancy loss. Chronic use of these medications can decrease fertility; however, discontinuation can reverse infertility. Nonsteroidal anti-inflammatory drugs should be avoided in women with fertility issues. Laboratory studies have found an increased risk of changes in ovary or testis formation in developing babies with ibuprofen exposure during pregnancy.

If I am taking ibuprofen, what should I know?

Nonsteroidal anti-inflammatory drugs are not recommended in early pregnancy or close to labor and delivery. If you are planning to become pregnant, you should contact your doctor to discuss your pregnancy plans. There has been some evidence that nonsteroidal anti-inflammatory drugs can increase the risk of miscarriage and harm to the developing baby. If you need a nonsteroidal anti-inflammatory drug for pain relief during pregnancy, your doctor can determine which nonsteroidal anti-inflammatory drug is safe and the correct dose and duration of the medication to minimize the risk of negative side effects.

Despite the lack of studies, nonsteroidal anti-inflammatory drugs are considered compatible while breastfeeding babies. Caution is advised in women who continue breastfeeding infants while taking nonsteroidal anti-inflammatory drugs.

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

This report provides a summary of available information about the use of ibuprofen 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 **ibuprofen** during and after pregnancy, contact http://www.womenshealth.gov/ (800-994-9662 [TDD: 888-220-5446]) or check the following links.

UpToDate: NSAIDs: Pharmacology and mechanism of action

U.S. National Library of Medicine: LACTMED: IBUPROFEN

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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.