



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

Pregnancy and Medicines

Q: Is it safe to use medicine while I am pregnant?

A: There is no clear-cut answer to this question. Before you start or stop any medicine, it is always best to speak with the doctor or nurse who is caring for you while you are pregnant. Read on to learn about deciding to use medicine while pregnant.

Q: How should I decide whether to use a medicine while I am pregnant?

A: When deciding whether or not to use a medicine in pregnancy, you and your doctor need to talk about the medicine’s benefits and risks.

- Benefits: what are the good things the medicine can do for me and my growing baby (fetus)?
- Risks: what are the ways the medicine might harm me or my growing baby (fetus)?

There may be times during pregnancy when using medicine is a choice. Some of the medicine choices you and your doctor make while you are pregnant may differ from the choices you make when you are not pregnant. For example, if you get a cold, you may decide to “live with” your stuffy nose instead

of using the “stuffy nose” medicine you use when you are not pregnant.

Other times, using medicine is not a choice—it is needed. Some women need to use medicines while they are pregnant. Sometimes, women need medicine for a few days or a couple of weeks to treat a problem like a bladder infection or strep throat. Other women need to use medicine every day to control long-term health problems like asthma, diabetes, depression, or seizures. Also, some women have a pregnancy problem that needs medicine treatment. These problems include severe nausea and vomiting, earlier pregnancy losses, or preterm labor.

Q: Where do doctors and nurses find out about using medicines during pregnancy?

A: Doctors and nurses get information from medicine labels and packages, textbooks, and research journals. They also share knowledge with other doctors and nurses and talk to the people who make and sell medicines.

The Food and Drug Administration (FDA) is the part of our country’s government that controls the medicines that can and can’t be sold in the United States. The FDA lets a company sell a medicine in the United States if it is safe to use and works for a certain problem. Companies that make medicines usually have to show FDA doctors and scientists whether birth defects or other problems occur in baby animals when the medicine is given to pregnant animals. Most of the time, drugs are not studied in pregnant women.

The FDA works with the drug companies to make clear and complete



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

labels. But in most cases, there is not much information about how a medicine affects pregnant women and their growing babies. Many prescription medicine labels include the results of studies done in pregnant animals. But a medicine does not always affect growing humans and animals in the same way. Here is an example:

A medicine is given to pregnant rats. If the medicine causes problems in some of the rat babies, it may or may not cause problems in human babies. If there are no problems in the rat babies, it does not prove that the medicine will not cause problems in human babies.

The FDA asks for studies in two different kinds of animals. This improves the chance that the studies can predict what may happen in pregnant women and their babies.

There is a lot that FDA doctors and scientists do not know about using medicine during pregnancy. In a perfect world, every medicine label would include helpful information about the medicine's effects on pregnant women and their growing babies. Unfortunately, this is not the case.

Q: How do prescription and over-the-counter (OTC) medicine labels help my doctor choose the right medicine for me when I am pregnant?

A: Doctors use information from many sources when they choose medicine for a patient, including medicine labels. To help doctors, the FDA created pregnancy letter categories to help explain what is known about using medicine during pregnancy. This system assigns letter categories to all prescription medicines. The letter category is listed in the label of a prescription medicine. The label states whether studies were done in pregnant women or pregnant animals and if so, what happened. Over-the-counter (OTC) medicines do not have a pregnancy letter category. Some OTC medicines were prescription medicines first and used to have a letter category. Talk to your doctor and follow the instructions on the label before taking OTC medicines.

Prescription Medicines

The FDA chooses a medicine's letter category based on what is known about the medicine when used in pregnant women and animals.

Pregnancy Category	Definition	Examples of Drugs
A	In human studies, pregnant women used the medicine and their babies did not have any problems related to using the medicine.	<ul style="list-style-type: none"> • Folic acid • Levothyroxine (thyroid hormone medicine)

FREQUENTLY ASKED QUESTIONS



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

Pregnancy Category	Definition	Examples of Drugs
B	<p>In humans, there are no good studies. But in animal studies, pregnant animals received the medicine, and the babies did not show any problems related to the medicine.</p> <p style="text-align: center;">Or</p> <p>In animal studies, pregnant animals received the medicine, and some babies had problems. But in human studies, pregnant women used the medicine and their babies did not have any problems related to using the medicine.</p>	<ul style="list-style-type: none"> • Some antibiotics like amoxicillin. • Zofran® (ondansetron) for nausea • Glucophage® (metformin) for diabetes • Some insulins used to treat diabetes such as regular and NPH insulin.
C	<p>In humans, there are no good studies. In animals, pregnant animals treated with the medicine had some babies with problems. However, sometimes the medicine may still help the human mothers and babies more than it might harm.</p> <p style="text-align: center;">Or</p> <p>No animal studies have been done, and there are no good studies in pregnant women.</p>	<ul style="list-style-type: none"> • Diflucan® (fluconazole) for yeast infections • Ventolin® (albuterol) for asthma • Zoloft® (sertraline) and Prozac® (fluoxetine) for depression
D	<p>Studies in humans and other reports show that when pregnant women use the medicine, some babies are born with problems related to the medicine. However, in some serious situations, the medicine may still help the mother and the baby more than it might harm.</p>	<ul style="list-style-type: none"> • Paxil® (paroxetine) for depression • Lithium for bipolar disorder • Dilantin® (phenytoin) for epileptic seizures • Some cancer chemotherapy

FREQUENTLY ASKED QUESTIONS



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

Pregnancy Category	Definition	Examples of Drugs
X	Studies or reports in humans or animals show that mothers using the medicine during pregnancy may have babies with problems related to the medicine. There are no situations where the medicine can help the mother or baby enough to make the risk of problems worth it. These medicines should never be used by pregnant women.	<ul style="list-style-type: none"> • Accutane® (isotretinoin) for cystic acne • Thalomid® (thalidomide) for a type of skin disease

The FDA is working hard to gather more knowledge about using medicine during pregnancy. The FDA is also trying to make medicine labels more helpful to doctors. Medicine label information for prescription medicines is now changing, and the pregnancy part of the label will change over the next few years.

OTC medicines

All OTC medicines have a *Drug Facts* label. The *Drug Facts* label is arranged the same way on all OTC medicines. This makes information about using the medicine easier to find. One section of the *Drug Facts* label is for pregnant women. With OTC medicines, the label usually tells a pregnant woman to speak with her doctor before using the medicine. Some OTC medicines are known to cause certain problems in pregnancy. The labels for these medicines give pregnant women facts about why and when they should not use the medicine. Here are some examples:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen (Advil®, Motrin®), naproxen (Aleve®), and aspirin (acetylsalicylate), can cause serious blood flow

problems in the baby if used during the last third of pregnancy (after 28 weeks). Also, aspirin may increase the chance for bleeding problems in the mother and the baby during pregnancy or at delivery.

- The labels for nicotine therapy drugs, like the nicotine patch and lozenge, remind women that smoking can harm an unborn child. While the medicine is thought to be safer than smoking, the risks of the medicine are not fully known. Pregnant smokers are told to try quitting without the medicine first.

Keep in mind that other things like caffeine, vitamins, and herbal remedies can affect the growing fetus. Talk with your doctor about cutting down on caffeine and ask which type of vitamin you should take. Never use an herbal product without talking to your doctor first.

Q: What if I'm thinking about getting pregnant?

A: If you are not pregnant yet, you can help your chances for having a healthy baby by planning ahead. Schedule a



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

pre-pregnancy checkup. At this visit, you can talk to your doctor about the medicines, vitamins, and herbs you use. It is very important that you keep treating your health problems while you are pregnant. Your doctor can tell you if you need to switch your medicine. Ask about vitamins for women who are trying to get pregnant. All women who can get pregnant should take a daily vitamin with folic acid (a B vitamin) to prevent birth defects of the brain and spinal cord. You should begin taking these vitamins before you become pregnant or if you could become pregnant. It is also a good idea to discuss caffeine, alcohol, and smoking with your doctor at this time.

Q: Is it safe to use medicine while I am trying to become pregnant?

A: It is hard to know exactly when you will get pregnant. Once you do get pregnant, you may not know you are pregnant for 10 to 14 days or longer. Before you start trying to get pregnant, it is wise to schedule a meeting with your doctor to discuss medicines that you use daily or every now and then. Sometimes, medicines should be changed, and sometimes they can be stopped before a woman gets pregnant. Each woman is different. So you should discuss your medicines with your doctor rather than making medicine changes on your own.

If you are pregnant or thinking about getting pregnant....

- Do not stop any prescribed medicines without first talking to your doctor.
- Talk to your doctor before using any over-the-counter medicine.

Q: What if I get sick and need to use medicine while I am pregnant?

A: Whether or not you should use medicine during pregnancy is a serious question to discuss with your doctor. Some health problems need treatment. Not using a medicine that you need could harm you and your baby. For example, a urinary tract infection (UTI) that is not treated may become a kidney infection. Kidney infections can cause preterm labor and low birth weight. An antibiotic is needed to get rid of a UTI. Ask your doctor whether the benefits of taking a certain medicine outweigh the risks for you and your baby.

Q: I have a health problem. Should I stop using my medicine while I am pregnant?

A: If you are pregnant or thinking about becoming pregnant, you should talk to your doctor about your medicines. Do not stop or change them on your own. This includes medicines for depression, asthma, diabetes, seizures (epilepsy), and other health problems. Not using medicine that you need may be more harmful to you and your baby than using the medicine.

For women living with HIV, the Centers for Disease Control and Prevention (CDC) recommends using zidovudine (AZT) during pregnancy. Studies show that HIV positive women who use AZT during pregnancy greatly lower the risk of passing HIV to their babies. If a diabetic woman does not use her medicine during pregnancy, she raises her risk for miscarriage, stillbirth, and some birth defects. If asthma and high blood pressure are not controlled during pregnancy, problems with the fetus may result.



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

Q: Are vitamins safe for me while I am pregnant?

A: Regular multivitamins and prenatal vitamins are safe to take during pregnancy and can be helpful. Women who are pregnant or trying to get pregnant should take a daily multivitamin or prenatal vitamin that contains at least 400 micrograms (µg) of folic acid. It is best to start taking these vitamins before you become pregnant or if you could become pregnant. Folic acid reduces the chance of a baby having a neural tube defect, like spina bifida, where the spine or brain does not form the right way. See our information on Folic Acid. Iron can help prevent a low blood count (anemia). It's important to take the vitamin dose prescribed by your doctor. Too many vitamins can harm your baby. For example, very high levels of vitamin A have been linked with severe birth defects.

Q: Are herbal remedies, “natural” products, or dietary supplements safe for me while I am pregnant?

A: Except for some vitamins, little is known about using dietary supplements while pregnant. Some herbal remedy labels claim they will help with pregnancy. But, most often there are no good studies to show if these claims are true or if the herb can cause harm to or your baby. Talk with your doctor before using any herbal product or dietary supplement. These products may contain things that could harm you or your growing baby during your pregnancy. In the United States, there are different laws for medicines and for dietary supplements. The part of the FDA that controls dietary supplements is

An Ounce of Prevention: Vaccines and Pregnancy

Vaccines protect your body against dangerous diseases. Some vaccines are not safe to receive during pregnancy. For some vaccines, the decision to give a vaccine during pregnancy depends on a pregnant woman's own situation. Her doctor may consider these questions before giving a vaccine:

1. Is there is a high chance she will be exposed to the disease?
2. Would the infection pose a risk to the mother or fetus?
3. Is the vaccine unlikely to cause harm?

The Advisory Committee on Immunization Practices recommends that Hepatitis B vaccination should be considered when women are at risk for developing Hepatitis B during pregnancy, and inactivated influenza vaccine should be considered for women who are pregnant during flu season. On the other hand, a pregnant woman who is not immune to rubella (German measles) is not given a rubella vaccine until after pregnancy. Talk with your doctor to make sure you are fully protected. The Centers for Disease Control and Prevention (CDC) provides vaccine guidelines for pregnant women. (<http://www.cdc.gov/vaccines/pubs/preg-guide.htm>)

the same part that controls foods sold in the United States. Only dietary supplements containing new dietary ingredients that were not marketed before October 15, 1994, submit safety information for review by the FDA. However, unlike medicines, herbal remedies and “natural products” are not approved by the FDA for safety or for what they say they will do. Most



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

have not even been evaluated for their potential to cause harm to you or the growing fetus, let alone shown to be safe for use in pregnancy. Before a company can sell a medicine, the company must complete many studies and send the results to the FDA. Many scientists and doctors at the FDA check the study results. The FDA allows the medicine to be sold only if the studies show that the medicine works and is safe to use.

Q: In the future, will there be better ways to know if medicines are safe to use during pregnancy?

A: At this time, drugs are rarely tested for safety in pregnant women for fear of harming the unborn baby. Until this changes, pregnancy exposure registries help doctors and researchers learn how medicines affect pregnant mothers and their growing baby. A pregnancy

exposure registry is a study that enrolls pregnant women who are using a certain medicine. The women sign up for the study while pregnant and are followed for a certain length of time after the baby is born. Researchers compare babies with mothers who used the medicine while pregnant to babies with mothers who did not use the medicine. This type of study compares large groups of pregnant mothers and babies to look for medicine effects. A woman and her doctor can use registry results to make more informed choices about using medicine while pregnant.

If you are pregnant and are using a medicine or were using one when you got pregnant, check to see if there is a pregnancy exposure registry for that medicine. The Food and Drug Administration has a list of pregnancy exposure registries (<http://www.fda.gov/womens/registries/default.htm>) that pregnant women can join. ■



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

For more information...

You can find out more about pregnancy and medicines from the National Women's Health Information Center (NWHIC) at 1-800-994-9662 or these organizations:

Food and Drug Administration

Phone Number(s): (888) 463-6332

(Consumer Information)

Internet Address: <http://www.fda.gov>

Food and Drug Administration

Office of Women's Health

General Information about Pregnancy

Exposure Registries

Internet Address: <http://www.fda.gov/womens/registries/default.htm>

National Institute of Child Health and Human Development

National Institutes of Health

Internet Address: <http://www.nichd.nih.gov>

Center for the Evaluation of Risks to Human Reproduction (CERHR)

National Institutes of Health

Internet Address: <http://cerhr.niehs.nih.gov>

American College of Obstetricians and Gynecologists (ACOG)

Phone Number(s): (800) 762-2264 x 192

(for publications requests only)

Internet Address: <http://www.acog.org>

March of Dimes Birth Defects Foundation

Phone Number(s): (914) 997-4488

Internet Address: <http://www.modimes.org>

Organization of Teratology Information Specialists (OTIS)

Phone Number(s): (866) 626-6847

Internet Address: <http://www.otispregnancy.org>

Medications and Mothers' Milk 2006

by Thomas W. Hale, RPh, PhD. Hale Publishing, 2006.



womenshealth.gov

1-800-994-9662

TDD: 1-888-220-5446

All material contained in the FAQs is free of copyright restrictions, and may be copied, reproduced, or duplicated without permission of the Office on Women's Health in the Department of Health and Human Services; citation of the source is appreciated.

This publication was reviewed by the following experts from the U.S. Food and Drug Administration:

Joseph M. Kaczmarczyk, DO, MPH

Medical Officer
Office of Women's Health

Alison Lemon, MHS
Public Health Educator
Office of Women's Health

Kathleen Uhl, MD
Assistant Commissioner for Women's Health

Sandra Kweder, MD
Deputy Director
Office of New Drugs
Center for Drug Evaluation and Research

Lisa Mathis, MD
Associate Director, Pediatric and Maternal Health Staff
Office of New Drugs
Center for Drug Evaluation and Research

Karen Feibus, MD
Medical Team Leader, Maternal Health Team
Office of New Drugs
Center for Drug Evaluation and Research

Richardae Araojo
Regulatory Reviewer, Maternal Health Team
Office of New Drugs
Center for Drug Evaluation and Research

Vasilios Frankos, PhD
Director
Division of Dietary Supplement Programs

Margaret Bash, MD, MPH
Captain, U.S. Public Health Service
Laboratory of Bacterial Polysaccharides

April 2007