

# Colace

## The safety of docusate sodium 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:**

Docusate sodium is considered compatible with pregnancy. There are limited human studies that have looked at the safety of docusate sodium during pregnancy, but available studies indicate that taking normal doses of docusate sodium during pregnancy should not be harmful to the developing baby. Other stool softeners are preferred. As with any medication, it is important to weigh the risks versus benefits before taking this medication during pregnancy.

#### **What is docusate sodium?**

Docusate sodium is a medication taken to soften stool in adults and children over 2 years old. Docusate sodium is available as brand name and generic medications. Docusate sodium is available in tablets, capsules, rectal enemas, or flavored syrup, and is taken once daily or in divided doses. It is available over-the-counter or by prescription from your doctor.

#### **What is docusate sodium used to treat?**

Docusate sodium is used to treat constipation. Constipation can occur in most individuals. Older age, poor dietary fiber intake, medications, gastrointestinal tract disorders, and pregnancy can increase the occurrence of constipation. Constipation is defined by less than 3 bowel movements per week, hard stool, painful bowel movements, and feeling some stool remaining after a bowel movement.

[Constipation during pregnancy](#) is caused by changes in hormone levels that decrease gastrointestinal movement and increase water absorption in the body. Constipation does not typically cause problems, but long-term constipation can lead to hemorrhoids, fecal impaction, rectal prolapse, and anal fissures.

#### **How does docusate sodium work?**

Docusate sodium works by increasing water elimination from the body and incorporation of water and fat in stool to allow for softer stool that is easier to pass during a bowel movement.

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

Women who have constipation during pregnancy are encouraged to try diet and lifestyle modifications before using stool softeners. Docusate sodium can be used during pregnancy, but other stool softeners are preferred and may be more effective in pregnant women. There are not enough human studies or case reports that have looked at the safety of this medication in pregnancy. Caution is advised when using docusate sodium during pregnancy.

### **Evidence from animal studies with docusate sodium:**

When given to pregnant rats in diets of 0.5% or 1% docusate as part of a three-generation study, docusate was not found to cause any negative effects on reproduction or development.

### **Evidence from human studies with docusate sodium:**

One case report in 1984 reported low magnesium levels that presented as jitteriness in a baby born to a mother who overused docusate sodium (100 mg to 200 mg per day) throughout her pregnancy. In a study of over 200 infants (1985-1992) exposed to docusate sodium during the first trimester or pregnancy, 3.9% (9 infants) developed birth defects, including one case of a cardiovascular defect and one case of polydactyly. No birth defects of the limbs, spine, genitalia, or cleft palate were reported. The authors of this study concluded the data were inconclusive of an association between docusate sodium and an increased risk of birth defects. As part of the Boston Drug Surveillance Program, 792 women who took docusate during the first trimester of pregnancy had no higher rates of birth defects than women not taking docusate during pregnancy.

**Bottom line:** Docusate sodium should be safe to use during pregnancy, but other interventions and medication may be preferred. There have been limited human studies that have looked at the safety of docusate sodium during pregnancy. Human studies found no conclusive increase in risk of birth defects with this medication.

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

If you are taking docusate sodium 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 docusate sodium, can I safely breastfeed my baby?**

It is unknown if docusate sodium passes into human breast milk, but it is expected to be systemically absorbed by a nursing infant. Other stool softeners are preferred in women who are breastfeeding. In a 1973 case report, a nursing infant developed diarrhea following use of docusate sodium and a stimulant laxative medication. It is advised to use caution in women who are breastfeeding infants on taking docusate sodium. The risks versus benefits of taking this medication should be weighed before use during breastfeeding.

**Bottom line:** In breastfeeding moms who are taking docusate sodium, caution is advised if continuing this medication. Docusate sodium is expected to be systemically absorbed in nursing infants.

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

Animal studies have not identified any negative effects of docusate sodium on fertility.

### **If I am taking docusate sodium, what should I know?**

Docusate sodium is considered safe during pregnancy. It is important to weigh the risks versus the benefits before using this medication during pregnancy. Available human studies suggest normal use of docusate sodium during pregnancy is not associated with an increase in risk of birth defects. Based on two separate case reports, overuse of docusate sodium during pregnancy or breastfeeding can cause low magnesium levels or diarrhea in infants.

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

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

You may find Pregistry's expert report about constipation [here](#), and reports about various other digestive health conditions as well as the individual medications used to treat digestive disorders [here](#). Additional information can also be found in the resources below.

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

Drugs.com: [Docusate Sodium Prescribing Information](#)

National Institute of Diabetes and Digestive and Kidney Diseases: [Definitions & Facts for Constipation](#)

## **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.