

Diclegis

The safety of doxylamine succinate-pyridoxine hydrochloride (diclegis) 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 is considered to have a low risk when used during pregnancy

What is doxylamine-pyridoxine?

Doxylamine-pyridoxine is an anti-emetic made of a combination of an antihistamine and a form of vitamin B6.

Doxylamine-pyridoxine is used to treat:

Doxylamine-pyridoxine is a prescription medication used to treat nausea and vomiting in pregnant women who do not respond to other conservative treatments.

How does doxylamine-pyridoxine work?

Doxylamine-pyridoxine contains the antihistamine doxylamine which helps to prevent stimulation of the inner ear that contributes to symptoms of nausea and vomiting. Pyridoxine is a B vitamin that is theorized to reduce symptoms of nausea and vomiting.

If I am taking doxylamine-pyridoxine, can it harm my baby?

A previous version of this medication called Bendectin (made up from doxylamine, pyridoxine, and dicyclomine) was used to treat nausea and vomiting during pregnancy. Animal studies have shown mixed effects on the developing baby. There have been 160 reports of birth defects associated with Bendectin use, although no direct correlation between these defects and Bendectin was proven. Older reports linked Bendectin to both a type of leukemia and gastric outlet obstruction, but these associations were never proven. Human studies found that Bendectin was safe for first trimester use and did not cause an increased risk of birth defects. A randomized controlled trial of pregnant women

during their first trimester who received doxylamine-pyridoxine found no increase in adverse effects on the developing baby. The opinion on the safety of Bendectin and the newer doxylamine-pyridoxine formulation remains mixed despite the large number of studies finding no harm to the baby. The American Congress of Obstetricians and Gynecologists recommends use of doxylamine-pyridoxine for management of nausea and vomiting or morning sickness in pregnancy.

If I am taking doxylamine-pyridoxine and become pregnant, what should I do?

It is important to talk to your doctor if you become pregnant and suffer from nausea and vomiting that does not respond to conservative treatment. You and your doctor can weigh the risks versus benefits of drug therapy.

If I am taking doxylamine-pyridoxine, can I safely breastfeed my baby?

Doxylamine-pyridoxine is expected to be excreted in breast milk. One side effect of the medication is drowsiness, which may affect the breastfeeding infant. Irritability and excitement are also possible side effects in breastfeeding infants. These side effects would only affect a breastfeeding infant if the medication doses were large or prolonged. Large doses of antihistamines can decrease levels of prolactin, the hormone that stimulates milk production, but it is unknown if doxylamine-pyridoxine causes this side effect. Because of all this, doxylamine products are not recommended during breastfeeding. It is important to talk to your doctor to weigh the risks and benefits of continuing on this medication while breastfeeding.

If I am taking doxylamine-pyridoxine, will it be more difficult to get pregnant?

Doxylamine-pyridoxine is used to treat nausea and vomiting in women who are already pregnant. There is no evidence about any effects this medication may have on future attempts to get pregnant.

If I am taking doxylamine-pyridoxine, what should I know?

It is important to speak with your doctor to determine if you need doxylamine-pyridoxine for nausea and vomiting during pregnancy. Your doctor may recommend trying conservative measures to address your symptoms before using this medication. Doxylamine-pyridoxine is not associated with an increased risk of birth defects. This medication compared to many other medications has been extensively studied in human trials without evidence of risk to the developing baby.

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

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

You may find Pregistry's expert report about nausea and vomiting [here](#) and reports about the individual medications used to treat digestive system disorders [here](#). Additional information can also be found in the resources below.

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

Diclegis.com: [Diclegis Prescribing Information](#)

Last Updated: 19-03-2019

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.

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