Doxylamine succinate-pyridoxine hydrochloride (Diclegis®)

This sheet is about exposure to doxylamine succinate-pyridoxine hydrochloride in pregnancy and while breastfeeding. This information is based on research studies. It should not take the place of medical care and advice from your healthcare provider.

What is doxylamine succinate-pyridoxine hydrochloride?

The combination of doxylamine succinate and pyridoxine hydrochloride is a medication that has been used to treat nausea and vomiting in pregnancy (NVP), also called "morning sickness." For more information on NVP, please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/.

Doxylamine succinate is an antihistamine. Antihistamines lessen the symptoms of allergic reactions and colds and help to treat insomnia (trouble sleeping). Pyridoxine hydrochloride is a form of vitamin B6. In the United States, the combination of doxylamine and pyridoxine can be found under the brand name Diclegis®. In Canada, it can be found under the brand name Diclectin®. Doxylamine succinate and/or pyridoxine hydrochloride are also available as over-the-counter medications.

Sometimes when women find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

I take doxylamine succinate-pyridoxine hydrochloride. Can it make it harder for me to get pregnant?

It is not known if doxylamine succinate-pyridoxine hydrochloride can make it harder to get pregnant.

Does taking doxylamine succinate-pyridoxine hydrochloride increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Doxylamine succinate-pyridoxine hydrochloride has not been shown to increase the chance of miscarriage.

Does taking doxylamine succinate-pyridoxine hydrochloride increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like doxylamine succinate-pyridoxine hydrochloride, might increase the chance of birth defects in a pregnancy.

Studies of hundreds of thousands of women have shown that taking doxylamine succinate-pyridoxine hydrochloride during pregnancy does not increase the chance of birth defects. Doxylamine succinate-pyridoxine hydrochloride has been recommended as a first-line treatment for NVP by the American College of Obstetricians and Gynecologists (ACOG) and by several medical organizations in Canada.

Does taking doxylamine succinate-pyridoxine hydrochloride in pregnancy increase the chance of other pregnancy-related problems?

Studies have found that taking doxylamine succinate-pyridoxine hydrochloride does not increase the chance of pregnancy-related problems such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

Does taking doxylamine succinate-pyridoxine hydrochloride in pregnancy affect future behavior or learning for the child?

Studies that have followed children from ages 2 to 7 years have not found a higher chance of behavior or learning problems after exposure to doxylamine succinate-pyridoxine hydrochloride during pregnancy.

Breastfeeding while taking doxylamine succinate-pyridoxine hydrochloride:

There are no studies looking at the combination of doxylamine succinate-pyridoxine hydrochloride while breastfeeding.

Antihistamines such as doxylamine can make people drowsy. It could cause drowsiness or irritability in a breastfeeding infant. If you suspect the baby has any symptoms (such as drowsiness or poor feeding), contact the child's healthcare provider.

The product label for Diclegis® recommends people who are breastfeeding not use this medication. However, the benefit of breastfeeding and using this medication might outweigh possible risks. Your healthcare providers can talk with you about using doxylamine succinate-pyridoxine hydrochloride and what treatment is best for you. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes doxylamine succinate-pyridoxine hydrochloride, could it affect fertility or increase the chance of birth defects?

Studies have not been done to see if doxylamine-pyridoxine could affect men's fertility (ability to get a woman pregnant) or increase the chance of birth defects in humans. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.

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