

Doxylamine succinate-pyridoxine hydrochloride (Diclegis®)

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

What is doxylamine succinate-pyridoxine hydrochloride?

The combination of 10mg of doxylamine succinate and 10mg of pyridoxine hydrochloride is a medication used to treat nausea and vomiting of pregnancy (NVP), also called “morning sickness.” For more information on NVP, please see the MotherToBaby fact sheet Nausea and Vomiting of Pregnancy (<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 (hard time 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® since 2013. In Canada, it can be found under the brand name Diclectin®. Diclegis® and Diclectin® are delayed-release tablets available by prescription. Delayed-release means that the tablet coating prevents the ingredients from being absorbed too quickly by the body. Doxylamine succinate and/or pyridoxine hydrochloride have also been available as over-the-counter medicines/supplements.

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

Based on the data available, it is not known if doxylamine succinate-pyridoxine hydrochloride can make it harder to become 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. Based on the studies reviewed, doxylamine succinate-pyridoxine hydrochloride does not increase the chance of miscarriage.

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

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Studies totaling hundreds of thousands of exposed pregnancies have not found that using doxylamine succinate-pyridoxine hydrochloride during pregnancy increases the chance of birth defects. The combination of doxylamine succinate and pyridoxine hydrochloride has been recommended as a first-line treatment for NVP by the American Congress of Obstetricians and Gynecologists (ACOG) and by several medical organizations in Canada for almost 20 years.

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 for 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 in children whose mothers used doxylamine succinate – pyridoxine hydrochloride during pregnancy.

Breastfeeding while taking doxylamine succinate-pyridoxine hydrochloride:

There are no formal studies looking at the effects of the combination of doxylamine succinate and pyridoxine hydrochloride on the breastfed infant.

Antihistamines that can make adults drowsy, such as doxylamine succinate, could cause drowsiness or irritability in a breastfeeding infant. Be cautious if you are breastfeeding a premature or newborn baby, or a baby who has breathing problems, or if your breastmilk supply has not been well established. If you suspect the baby has any symptoms such as drowsiness or poor feeding, contact the child's healthcare provider.

Pyridoxine hydrochloride readily enters breast milk; it has not been associated with any problems in breastfeeding infants when taken in amounts similar to that present in Diclegis (10mg).

According to the manufacturer of Diclegis, women prescribed this medication should not breastfeed. But, the benefit of using doxylamine succinate - pyridoxine hydrochloride may 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 of your breastfeeding questions.

If a man takes doxylamine succinate-pyridoxine hydrochloride, could it affect a man's fertility (ability to get a woman pregnant) or increase the chance of birth defects in a partner's pregnancy?

Studies have not been done to see if doxylamine-pyridoxine could affect a man's fertility or increase the chance of birth defects in a partner's pregnancy. In general, exposures that men have are unlikely to increase the 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.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://mothertobaby.org).

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