Doxylamine succinate-pyridoxine hydrochloride

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 providers.

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/pdf/).

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 has been sold under the name Diclegis® since 2013. In Canada, it has been sold 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 may also be available as over-the-counter medicines.

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.

I just found out I am pregnant. Should I stop taking doxylamine succinate-pyridoxine hydrochloride?

Talk with your healthcare providers before making any changes to how you take your medication(s).

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

Miscarriage can occur in any pregnancy. Based on the data available, doxylamine succinate-pyridoxine hydrochloride does not increase the chance for 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 pregnant women 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.

Could taking doxylamine succinate-pyridoxine hydrochloride cause other pregnancy complications?

Taking doxylamine succinate-pyridoxine hydrochloride has not been found to increase the chance of pregnancy complications.

Does taking doxylamine succinate-pyridoxine hydrochloride in pregnancy cause long-term problems in behavior or learning for the baby?

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.

Can I breastfeed 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 mom drowsy, such as doxylamine succinate, could cause drowsiness or irritability in a breastfeeding infant. 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, people prescribed this medication should not breastfeed. Be especially cautious if you are breastfeeding a premature or newborn baby, or one with a history of breathing issues. If you suspect the baby has any symptoms such as drowsiness or poor feeding, contact the child’s healthcare provider. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

**If a male takes doxylamine-pyridoxine, could it affect the ability to conceive a pregnancy or increase the chance of birth defects?**

There are no studies looking at possible risks to a pregnancy when a male takes doxylamine-pyridoxine. In general, exposures that fathers or sperm donors 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.