



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Doxylamine succinate-pyridoxine hydrochloride (Diclegis®|Diclectin®) and Pregnancy

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to the combination of doxylamine succinate and pyridoxine hydrochloride may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is doxylamine succinate-pyridoxine hydrochloride?

Doxylamine succinate is a medication that has been used as an antihistamine and a sleeping aid. Antihistamines lessen the symptoms of allergic reactions, insomnia and colds. Pyridoxine hydrochloride is a form of vitamin B6.

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 (<http://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/pdf/>).

In the United States, the combination of doxylamine and pyridoxine has been sold under the name Diclegis® since 2013. Many years ago, it was sold under the name Bendectin®. In Canada, it has been sold under the brand name Diclectin® since 1979.

Diclegis® and Diclectin® are delayed-release tablets available by prescription. Delayed-release means that the tablet coating prevents the ingredients from being immediately absorbed by the body. For this reason, it is important to take the medicine regularly and on a set schedule (not just as needed) in order to obtain the maximum benefits. Doxylamine succinate and/or pyridoxine hydrochloride may also be available as over-the-counter medicine (OTC). OTC forms likely do not have the delayed release coating and might not be the same doses as the prescription form.

Did the manufacturer stop making Bendectin® because it was unsafe?

No. Bendectin® was used by over 33 million women worldwide from 1956 when it was first approved by the U.S. FDA through 1983. In the 1970s, lawsuits filed against the manufacturer claimed that the use of Bendectin® in pregnancy caused babies to be born with birth defects. However, there was no scientific evidence to back up these claims. In 1983, Bendectin® production was stopped because of the increased costs of these lawsuits, *not* because Bendectin® was ever determined to be unsafe for use in pregnancy. The FDA released a statement in 1983 and again in 1999 emphasizing that the withdrawal was not related to safety. In 2013 the FDA classified Diclegis® as not having risk to the fetus and approved the use of Diclegis® for treatment of NVP.

Is it okay to use doxylamine succinate-pyridoxine hydrochloride during pregnancy?

Yes. Doxylamine succinate-pyridoxine hydrochloride is well studied in its use to treat NVP. Studies totaling hundreds of thousands of exposed pregnant women have not found its use during pregnancy to increase the chance of birth defects or other adverse pregnancy outcomes. The combination of doxylamine succinate and pyridoxine hydrochloride is currently recommended as a first-line treatment for NVP by the American Congress of Obstetricians and Gynecologists (ACOG) and by several medical organizations in Canada. In addition, keeping your NVP under control might help to keep you out of the hospital for dehydration caused by vomiting.

If I need to take more than the standard dose of doxylamine succinate-pyridoxine hydrochloride, will that increase the risk to the pregnancy?

Probably not. Researchers have looked at the use of doxylamine succinate-pyridoxine hydrochloride in pregnancy when women were prescribed more than the standard dose due to the severity of their symptoms and/or their body weight. There was no increase in the number of adverse pregnancy outcomes for those who used higher doses compared to those who used the standard dose. However, you should always talk with your health care provider before making any changes in your medications.

Could this medication cause long-term effects on my children if I take it during pregnancy?

It is unlikely. Studies that have followed children from ages two to seven years did not find any suggestion of problems associated with doxylamine succinate – pyridoxine hydrochloride when used by their mother during pregnancy.

Can I take doxylamine succinate-pyridoxine hydrochloride while breastfeeding?

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 could increase the chance of drowsiness in your breastfeeding infant, especially when used on a regular basis. Pyridoxine hydrochloride is excreted into breast milk but it has not been associated with any problems in breastfeeding infants. Be sure to talk to your health care provider about all your choices for breastfeeding.

What if the father of the baby takes doxylamine succinate-pyridoxine hydrochloride?

There are no studies looking at possible risks to a pregnancy when the father takes doxylamine-pyridoxine. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy (<http://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>).

References Available By Request

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