Thalidomide

This sheet talks about exposure to thalidomide in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is thalidomide?
Thalidomide is a sedative that also changes the body’s immune response and reduces the ability of the body to grow new blood vessels. Thalidomide was one of the first medications recognized to cause birth defects in humans. Thalidomide was not released in the United States until 1998. It has been used to treat several medical conditions, such as leprosy, certain types of cancer, inflammatory bowel disease and complications from HIV infection. It is sold under the brand name Thalomid®.

I take thalidomide. Can it make it harder for me to get pregnant?
There has been one small study that looked at women who had inflammatory bowel disease and were treated with thalidomide. This study suggested exposure to thalidomide might reduce the number of eggs in the ovaries. It is not clear if this would affect fertility. Further study is needed.

Because thalidomide can cause birth defects when taken early in pregnancy, often before a woman recognizes that she is pregnant, it is very important that effective methods of birth control be used correctly and all of the time. It is recommended that two different and reliable methods of birth control be used if a woman is taking thalidomide. Thalidomide may decrease the effectiveness of oral contraceptives (birth control pills). The manufacturer developed the REMS (Risk Evaluation and Mitigation Strategy) program (formerly known as the S.T.E.P.S.® program) to help prevent exposure to pregnant women.

After I stop taking thalidomide, how long should I wait to become pregnant?
In healthy adults, almost all of this medication would likely be gone from the body within two days of taking a single dose. To be safe, it has been recommended that women stop the use of thalidomide one month before trying to get pregnant.

If I get pregnant while taking thalidomide, what should I do?
Thalidomide should be stopped right away if you miss your period, you have a positive pregnancy test, or have abnormal menstrual bleeding. If you become pregnant during treatment, contact your healthcare providers right away. Your healthcare providers will discuss the possibilities for prenatal screening and/or testing.

Does taking thalidomide increase the chance for miscarriage?
Yes. If a woman takes thalidomide in pregnancy, there is a chance for pregnancy loss and infant death. The cause of death has been attributed to the birth defects caused by the thalidomide exposure.

Does taking thalidomide in the first trimester increase the chance of birth defects?
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. Thalidomide can increase this chance for birth defects.

When a woman takes thalidomide early in her pregnancy (between the 20th and 36th day after conception or the 34-50th day after the start of the last period), there is a chance of at least 20% or more to have a baby with birth defects. The birth defects usually seen in babies exposed to thalidomide during pregnancy are very short or missing arms and legs, missing parts of the ears, and deafness. There is also a risk of other problems such as missing or small eyes, paralysis of the face, poor growth, intellectual disabilities, and malformations of the heart, kidney, genitals (sex organs), and
gastrointestinal tract (stomach and intestines). The risk of birth defects if the medication is taken after the first trimester is unknown.

**Does taking thalidomide in pregnancy cause long-term problems in behavior or learning for the baby?**

The only long-term studies of thalidomide exposure during pregnancy was done on children who were born with birth defects. Some of these children have intellectual disabilities or have behavioral conditions such as autism. The possible long-term effects on children exposed to thalidomide but who were not born with physical birth defects are unknown.

**Can I breastfeed while taking thalidomide?**

This is not recommended. Thalidomide has not been studied during breastfeeding. Based on its chemical properties, it is expected to pass into breast milk. The drug may cause drowsiness in a breastfed infant, but the exact effects of thalidomide on the breastfed infant are unknown. Until more is known, it is not recommended that women breastfeed while taking thalidomide. Talk with your healthcare provider about all of your breastfeeding questions.

**If a man takes thalidomide, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?**

There are no reports in the literature to suggest that the use of thalidomide in men might increase the chance of birth defects or fertility problems. However, thalidomide can get into semen, often at levels higher than found in blood. It is recommended that men taking thalidomide use latex or synthetic condoms during intercourse, and for 28 days after stopping thalidomide.

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 at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

**Please click here for references.**