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 thalidomide 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 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.

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.

Can thalidomide make it more difficult for me to become 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 STEPS (System for Thalidomide Education and Prescribing Safety) program to help prevent exposure to pregnant women.

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

Can taking thalidomide during pregnancy cause birth defects in my baby?
Yes. When a pregnant woman takes thalidomide early in pregnancy (between the 20th and 36th day after conception or the 34-50th after the start of the last period), there is a risk 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 extremely 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.

Will taking thalidomide have an effect on my baby’s behavior and development?
The only long-term studies of thalidomide exposure during pregnancy have been done on children 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.

If I get pregnant while taking thalidomide, what should I do?

Thalidomide should be stopped immediately if you miss your period, you have a positive pregnancy test, or have abnormal menstrual bleeding. If you become pregnant during treatment, contact your health care provider right away. Your health care provider will discuss the possibilities for prenatal testing. Prenatal testing involves a detailed ultrasound to look at the baby’s body and organs. Ultrasound can visualize many birth defects, but is not able to detect all potential fetal problems caused by a thalidomide exposure.

Can I take thalidomide while breastfeeding?

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. Be sure to talk to your health care about the best way to feed your baby.

If a man uses thalidomide, will it cause birth defects in his children?

There are no reports in the literature that suggest the use of thalidomide in men is associated with an increased risk of birth defects. However, thalidomide is excreted in 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. For more information on paternal exposures, in genera, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

References: