Thalidomide

This sheet is 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 medication that changes the body's immune response and lowers the ability of the body to grow new blood vessels. Thalidomide was introduced in Germany and other countries in the 1960s as a sedative. It is one of the first medications known to cause birth defects in humans. It was prescribed to people who were pregnant to treat nausea and vomiting in early pregnancy. Thalidomide was not released in the United States until 1998. It has been used to treat several conditions, such as leprosy, cancer, inflammatory bowel disease, and complications from HIV infection. It is sold under the brand name Thalomid®.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. The product label for thalidomide recommends people who are pregnant not use this medication. However, the benefit of using thalidomide may outweigh possible risks. It is important to talk with your healthcare providers before making any changes to how you take this medication. They can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

If you miss your period, get pregnant, have a positive pregnancy test, or have unusual menstrual bleeding while taking thalidomide, contact your healthcare providers right away.

I am taking thalidomide, but I would like to stop taking it before getting pregnant. How long does the drug stay in my body?

People eliminate medications at different rates. In healthy adults, it takes up to 2 days, on average, for most of the thalidomide to be gone from the body. It has been recommended that people stop using thalidomide 1 month before trying to get pregnant.

Thalidomide can cause birth defects when taken early in pregnancy, often before a person knows that they are pregnant. It is recommended that 2 different and reliable methods of birth control be used if a person is taking thalidomide. It is very important that effective methods of birth control be used correctly and at all times. Thalidomide may lower how well oral contraceptives (birth control pills) work. The manufacturer of thalidomide developed the REMS (Risk Evaluation and Mitigation Strategy) program (formerly known as the S.T.E.P.S.® program) to help prevent thalidomide exposure in people who are pregnant. Be sure to talk to your healthcare provider about the 2 birth control methods you should use when taking thalidomide.

I take thalidomide. Can it make it harder for me to get pregnant?

There has been 1 small study that looked at people with inflammatory bowel disease who were treated with thalidomide. This study suggested exposure to thalidomide might lower the number of eggs in the ovaries, which could make it harder to get pregnant.

Does taking thalidomide increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. If a person takes thalidomide in pregnancy, there is an increased chance for miscarriage.

Does taking thalidomide 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. Thalidomide can increase the chance for birth defects above the background risk.

When a person who is pregnant takes thalidomide early in pregnancy (between the 20th and 36th day after conception or the 34-50th day after the start of the last period), there is at least a 20% chance of birth defects. The birth defects usually seen with thalidomide exposure during pregnancy are very short or missing arms and legs, missing parts of the ears, and deafness. There is also a chance of other problems such as missing or small eyes, paralysis of the face, and defects in the heart, kidney, genitals (sex organs), and gastrointestinal tract (stomach and intestines). The chance of

birth defects if thalidomide is taken after the first trimester is unknown.

Does taking thalidomide in pregnancy increase the chance of other pregnancy-related problems?

Exposure to thalidomide in pregnancy has been associated with poor growth. It is not known if thalidomide can cause other pregnancy-related problems, such as preterm delivery (birth before week 37).

Does taking thalidomide in pregnancy affect future behavior or learning for the child?

Long-term studies of thalidomide exposure during pregnancy were done on children who were born with birth defects. Some have intellectual disabilities or other conditions such as autism. It is not known how thalidomide may affect behavior or learning for children exposed to thalidomide who were not born with physical birth defects.

What screenings or tests are available to see if my pregnancy has birth defects or other issues?

Prenatal ultrasounds can be used to screen for some birth defects. Ultrasound can also be used to monitor the growth of the pregnancy. Talk with your healthcare provider about any prenatal screenings or testing that are available to you. There are no tests available during a pregnancy that can tell if there has been any effect on behavior or ability to learn.

Breastfeeding while taking thalidomide:

Thalidomide has not been studied for use in breastfeeding. Based on its chemical properties, it is expected to pass into breast milk. The drug may cause drowsiness in a breastfed infant, but exact effects of thalidomide on breastfed infants are unknown.

The product label for thalidomide recommends people who are breastfeeding not use this medication. However, the benefit of using thalidomide may outweigh possible risks. Your healthcare provider can talk with you about using thalidomide and what treatment is best for you. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Studies have not been done to see if thalidomide could affect male fertility or increase the chance of birth defects above the background risk. Thalidomide can get into semen, often at levels higher than found in blood. It is recommended that males use latex or synthetic condoms during intercourse while they are taking thalidomide and for 28 days after stopping the medication. For more information on paternal exposures in general, please see the MotherToBaby fact sheet 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.

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