Thalidomide (Thalomid®)

This sheet is about exposure to thalidomide in pregnancy and breastfeeding. This information is based on published research studies. It should not take the place of medical care and advice from your healthcare provider.

What is thalidomide?

Thalidomide is a medicine that changes how the immune system works and reduces the body's ability to grow new blood vessels. It was first introduced in Germany in the 1960s as a sleeping pill. It was also given to pregnant women to help with nausea and vomiting. Later, it was discovered that it could cause serious birth defects. It became one of the first medicines known to cause birth defects in humans.

Thalidomide was not approved in the United States until 1998. Today, it is used to treat certain conditions, including leprosy, some cancers, inflammatory bowel disease, and complications from HIV. It is sold under the brand name Thalomid®.

Sometimes when women 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 not using this medication during pregnancy. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Your healthcare providers 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 provider 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?

The time it takes the body to metabolize (to process) medication is not the same for everyone. In healthy non-pregnant 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 for 1 month before trying to get pregnant.

Thalidomide can cause birth defects when taken early in pregnancy, often before a pregnancy is recognized. It is recommended that 2 different and reliable methods of birth control be used if a woman is taking thalidomide. It is very important that effective methods of birth control be always used correctly. Thalidomide may lower how well oral 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 pregnancy 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?

A small study of people with inflammatory bowel disease found that treatment with thalidomide may 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 of miscarriage.

Does taking thalidomide increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like thalidomide, might increase the chance of birth defects in a pregnancy. Thalidomide can increase the chance of birth defects above the background risk.

When thalidomide is taken 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% (1 in 5) chance of birth defects. The birth defects usually seen are very short or missing arms and legs, missing parts of the ears, and hearing loss. 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 linked to poor growth of the fetus. It is not known if thalidomide can increase the chance of 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 if or how thalidomide might affect behavior or learning in 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 pregnancy that can tell how much effect there could be on future behavior or learning.

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 might cause drowsiness in a breastfed infant, but exact effects of thalidomide (if any) on breastfed infants are unknown.

The product label for thalidomide recommends not using this medication while breastfeeding. 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 man takes thalidomide, could it affect his fertility or increase the chance of birth defects?

Studies have not been done to see if thalidomide could affect men's fertility (ability to get a partner pregnant) or increase the chance of birth defects. Thalidomide can get into semen, often at levels higher than found in blood. It is recommended that men 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 Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here to view references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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