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Thalidomide and Pregnancy

This sheet talks about the risks that exposure to thalidomide can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. This information should not take the place of medical care and advice from your health care provider.

What is thalidomide?

Thalidomide is a sedative agent 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 drugs recognized to cause birth defects in humans. Although thalidomide was not released in the United States until 1998, it is now being studied for treatment of many different, serious medical problems.

After I stop taking thalidomide, how long should I wait to become pregnant?

There are no studies on pregnancy outcome in women who only used thalidomide prior to conception. All infants known to have thalidomide-related birth defects were exposed during the first trimester of pregnancy. It is known that the half-life of thalidomide is 8.7 hours, which is the time it takes for 50% of the drug to be cleared from your body. Therefore, after a few days to a week, any remaining drug level would be fairly low.

To be safe, it is recommended that women stop use of thalidomide one month before conception to reduce the risk of thalidomide-related birth defects.

Can thalidomide make it more difficult for me to become pregnant?

No. To date, there are no reports linking thalidomide use and infertility. However,

because thalidomide can damage the developing fetus early in pregnancy, often before a woman recognizes she is pregnant, it is important that very effective methods of birth control be used. Therefore, it is recommended that two different and reliable methods of birth control be used if a woman is taking thalidomide. The manufacturer developed the STEPS (System for Thalidomide Education and Prescribing Safety) program to help prevent exposure to pregnant women.

Can taking thalidomide during pregnancy cause birth defects in my baby?

Yes. When a pregnant woman takes thalidomide 34-50 days (4.5 to 7 weeks) after the beginning of her last menstrual period, there is a risk of approximately 20% or greater to have a baby with birth defects such as extremely short or missing arms and legs, missing ears (both outside and inside), and deafness. There is also a risk of other problems such as heart defects, missing or small eyes, paralysis of the face, kidney abnormalities, gastrointestinal abnormalities, poor growth and mental retardation. The risk for fetal damage if the drug 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 were mentally retarded or had behavioral conditions such as autism. The long-term effects on children exposed to thalidomide but who were not born with birth defects are unknown.

Does thalidomide cause an increased risk for miscarriage or infant death?

Yes. The fetal and infant death rate with maternal thalidomide use is estimated to be as high as 40% or greater. The cause of death has been attributed to the severe birth defects caused by the thalidomide exposure.

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

You should contact your health care provider immediately to discuss your options. These include whether to discontinue your medication and also the possibilities for prenatal testing. Prenatal testing would most likely involve a detailed ultrasound to look at fetal structure. Ultrasound can visualize many birth defects, but is not able to detect all potential fetal problems caused by a thalidomide exposure.

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. Yet, as the information is limited, the manufacturer recommends that men taking thalidomide should always use condoms during intercourse as a precautionary measure.

Can I take thalidomide while breast-feeding?

Thalidomide has not been studied during breast-feeding. Many drugs do get into the breast milk, so it is possible that

thalidomide gets into the milk as well. However, the effects of thalidomide on the breast-fed infant are unknown. Theoretically, the drug can cause drowsiness in the breast-fed infant. Until more is known, it is not recommended that women breast-feed while taking thalidomide.

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*If you have questions about the information on this fact sheet or other exposures during pregnancy, call **OTIS** at 1-866-626-6847.*