



For more information regarding OTIS or a Teratology Information Service in your area, call OTIS Information at (866) 626-6847 or visit us online at: www.OTISpregnancy.org.

Thalidomide and Pregnancy

The information below will help you determine if your prenatal exposure to thalidomide will increase the fetal risk above the background risk. With every pregnancy, any woman has a 3 to 5 percent chance to have a baby with a birth defect.

Thalidomide

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 never released in the United States until 1998, it is now being studied for treatment of many different, serious medical problems.

After a woman stops taking thalidomide, how long should she 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 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, most health care providers recommend that two different methods of birth control be used if a woman is taking thalidomide.

Can taking thalidomide during pregnancy cause birth defects?

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 problems 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, 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 a 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 a woman gets pregnant while taking thalidomide, what should she do?

She should immediately contact her health care provider to discuss her options. These include whether to discontinue her 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 thalidomide be taken 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. Therefore, until more is known, it is recommended that women taking thalidomide not breast-feed. Theoretically, the drug can cause drowsiness in the breast-fed infant.



**July 2003
Copyright by OTIS
Reproduced by permission**

ORGANIZATION
OF TERATOLOGY
INFORMATION
SERVICES

References:

- Brooks C, et al: Linear growth of children with limb deformities following exposure to thalidomide in utero. *Acta Paediatr Scand*: 1977; 66: 673-675.
- Castilla E, et al: Thalidomide, a current teratogen in South America. *Teratology*: 1996; 54: 273-277.
- Gollop T, et al: Prenatal diagnosis of thalidomide syndrome. *Prenat Diagn*: 1987; 7: 295-298.
- Smithells R: Recognition of thalidomide defects. *J Med Genet*: 1992; 29: 716-723.
- Sterling D, et al: Thalidomide: A Surprising Recovery. *J Am Pharm Assn*: 1997; 3: 306-313.
- Stromland K, et al: Thalidomide embryopathy: revisited 27 years later. *Acta Ophthalmol (Copen)*: 1993; 71: 238-245.
- Tseng S, et al: Rediscovering thalidomide: A review of its mechanism of action, side effects and potential uses. *J Am Acad Dermatol*: 1996; 35:969-979.
- Thalidomide symposium: Papers presented at the 26th meeting of the Teratology Society, July 6-10, 1986, Boston, Mass. *Teratology*: 1988; 38: 201-251.