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## Enzyme Replacement Therapy for Treatment of Gaucher Disease in Pregnancy and Breastfeeding

This sheet talks about the risks that exposure to enzyme replacement therapy (ERT) 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 enzyme replacement therapy?***

Enzyme replacement therapy is a treatment of Gaucher disease. People with Gaucher disease have a deficiency of the enzyme called glucocerebrosidase. This enzyme helps break down fatty substances in the body, and when the enzyme is deficient, fatty substances build up in parts of the body and cause damage.

(For more information, please see the OTIS fact sheet [Gaucher Disease in Pregnancy.](#))

The treatment replaces the enzyme that is missing or not working properly with a synthetic form of the enzyme. These replacement enzymes are typically given IV (intravenously), in high doses every two weeks. Current available synthetic enzymes are Cerezyme® (imiglucerase), VPRIV® (velaglucerase) and Ceredase® (alglucerase)

In many individuals with Gaucher disease, especially Type I, enzyme therapy can reduce the enlargement of the liver and spleen and can help maintain normal blood factors.

### ***I have Gaucher disease and am currently on enzyme replacement therapy. I would like to become pregnant. What should I do?***

Current guidelines suggest that a woman with Gaucher disease planning a pregnancy should consider enzyme replacement therapy prior to conception to reach her optimal health status. If you become pregnant on enzyme replacement therapy, you

should discuss continuation of treatment throughout pregnancy with your health care provider.

### ***I have been on enzyme replacement therapy and just found out I am pregnant. Should I stop?***

No. You should not stop taking any medication without first talking to your health care provider. The current recommendation is to not stop treatment if pregnancy occurs. Studies suggest that continued use reduces pregnancy, delivery, and postpartum complications. Specifically, treatment during pregnancy may decrease the risk for miscarriage and bleeding.

If you have Gaucher disease but have not been experiencing symptoms, it may not be necessary to start enzyme replacement therapy in pregnancy. However, if symptoms do start in pregnancy, enzyme replacement therapy treatment can be considered. Studies have suggested that treatment with enzyme replacement prior to and during pregnancy allows the woman to be in the best health to tolerate the demands of pregnancy on the body.

### ***Can taking enzyme replacement therapy during pregnancy cause a birth defect in my baby?***

Current information does not suggest an increased risk for birth defects when enzyme replacement therapy is used during pregnancy. The manufacturer of imiglucerase has a

pregnancy registry, and data from this registry have not found enzyme replacement therapy use in pregnancy to increase the risk for birth defects. Additional case reports of ERT use in pregnancy or prior to pregnancy have not supported an increased risk for birth defects.

***Is it safe for me to continue ERT while I am breastfeeding?***

There are no studies looking at enzyme replacement therapies and breastfeeding. There is one case report evaluating the transfer of the enzyme into breast milk. In this case, there was only a small amount detected in the first milk produced following administration of the enzyme to the mother. The replacement enzyme is similar to the naturally occurring enzyme in the infant, and the enzyme is likely to be digested in the infant's gastrointestinal tract, suggesting very low risk to a nursing infant.

***Is there a concern if my partner was on ERT when I got pregnant?***

There are currently no studies looking at men on enzyme replacement therapy at the time of conception. Medications that the father takes do not increase risk to a pregnancy because the father does not share a blood connection with the developing baby. For more information, please see the OTIS fact sheet [Paternal Exposures and Pregnancy](#).

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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**.*

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**Selected References**

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