Miglustat (Zavesca®) and Pregnancy

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to miglustat may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care professional.

What is miglustat?

Zavesca® (miglustat) is a medication taken by mouth for the treatment of mild to moderate Type I Gaucher disease. It is a type of treatment used in individuals where enzyme replacement therapy is not recommended.

People with Gaucher disease have a deficiency of the enzyme called glucocerebrosidase. This enzyme helps break down fatty substances in the body, and when this enzyme is deficient, fatty substances build up and can cause organ damage. Miglustat works in the body to limit the amount of the fatty substance being made.

(I am currently taking miglustat and would like to become pregnant. What should I do?

It is recommended that miglustat treatment be stopped three months prior to conception. Please discuss any treatment changes, including stopping miglustat, with your health care provider prior to making any changes.

I have been taking miglustat 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.

Can taking miglustat during pregnancy cause a birth defect?

There have been no studies or reports of miglustat use during pregnancy. It is thought to cross the placenta. As the risk to human pregnancy is unknown, it is not recommended for use in pregnancy.

Is it safe for me to take miglustat while I am breastfeeding?

There are no studies looking at miglustat and breastfeeding, and it is unknown whether or not it passes into breast milk. It is currently not recommended for use while breastfeeding. Be sure to talk to your health care provider about all your options for breastfeeding.

Is there a concern if my partner was taking miglustat when I got pregnant?

There are no studies looking at paternal use of miglustat prior to or at the time of conception. Animal studies in rats found that miglustat exposure decreased sperm production, which reduced fertility or the ability to reproduce. In humans, one report did not find miglustat use in men to affect the
production of sperm or their fertility. In general, medications that the father takes do not increase risk to a pregnancy. For more information, please see the OTIS fact sheet Paternal Exposures and Pregnancy at http://www.mothertobaby.org/files/paternal.pdf

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Selected References


www.zavesca.com

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