



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

For more information about us or to find a service in your area,
call **(866) 626-6847**. Visit us online at **www.MotherToBaby.org**.

Find us! Facebook.com/MotherToBaby or @MotherToBaby on Twitter

Miglustat (Zavesca®)

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 provider.

What is miglustat?

Miglustat (Zavesca®) is a medication that has been used for treatment of mild to moderate Type I Gaucher disease and Niemann-Pick disease, type C. It is used in individuals with Gaucher disease when enzyme replacement therapy is not recommended.

People with Gaucher disease have a deficiency of the enzyme called glucocerebrosidase (gloo-co-se-ruh-BRO-si-dace). This enzyme helps break down fatty substances in the body. When this enzyme is missing or not working, fatty substances build up and can cause organ damage. Miglustat works in the body to limit the amount of the fatty substance being made. For more information, see the MotherToBaby fact sheet Gaucher Disease in Pregnancy at <https://mothertobaby.org/fact-sheets/gaucher-disease-pregnancy/pdf/>.

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

It is important to discuss your pregnancy plans and any treatment changes, such as stopping miglustat, with your health care providers. Having this discussion prior to a pregnancy allows time to consider risks and benefits of treatment options for the pregnancy.

I have been taking miglustat and just found out I am pregnant. Should I stop?

You should not stop taking any medication without first talking to your health care providers.

Can taking miglustat during my pregnancy increase the chance of miscarriage?

This is unknown. There have been no studies or reports of miglustat use during pregnancy in humans. Studies in animals found a greater chance of pregnancy loss. Until further studies are performed, the risks of using miglustat in pregnancy are not clear.

Can taking miglustat during pregnancy cause a birth defect or other pregnancy complications?

There have been no studies or reports of miglustat use during pregnancy in humans. Studies in animals found a greater chance of low birth weight. Until more studies are performed, the risks of using miglustat in pregnancy are not known.

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

This is unknown. There are no studies looking at miglustat use while breastfeeding. It is possible that miglustat could enter breastmilk, but studies are needed to confirm this. The effects on a nursing infant are unknown. More information is needed in order to know if miglustat would affect a nursing infant. Be sure to talk to your health care provider about all of your medications and breastfeeding questions.

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

There are no studies looking at possible risks to a pregnancy when the father takes miglustat. Animal studies in rats found that miglustat exposure decreased sperm production, which reduced fertility (ability to get partner pregnant). However, this was not found in all animal studies. In humans, one report did not find miglustat use in men to affect the production of sperm or their fertility. In general, exposures that fathers have are unlikely to increase risks to a

pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

Selected References

- Granovsky-Grisaru, S et al. The management of pregnancy in Gaucher disease. 2011. *Thromb Haemost*, 156:3-8.
- Hollak, C et al. Miglustat (Zavesca®) in type I Gaucher disease: 5-year results of a post-authorisation safety surveillance programme. 2009. *Pharmacoepidemiol Drug Saf* 18:770-777.
- Miglustat (Zavesca®) Product Label. [Accessed 8/2017]
https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021348s010lbl.pdf

August, 2017