This sheet is about exposure to siponimod in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is siponimod?

Siponimod (Mayzent®) is a medication approved to treat relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. For information on multiple sclerosis, please see the MotherToBaby fact sheet at: https://mothertobaby.org/fact-sheets/multiple-sclerosis/.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

I am taking siponimod, but I would like to stop taking it before becoming pregnant. How long does the drug stay in my body?

People eliminate medication at different rates. In healthy adults it takes up to 10 days, on average, for most of the siponimod to be gone from the body.

I take siponimod. Can it make it harder for me to get pregnant?

It is not known if siponimod can make it harder to become pregnant.

Does taking siponimod increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. According to the product label, experimental animal studies reported an increase in pregnancy loss. Studies have not been done in human pregnancy to see if siponimod increases the chance for miscarriage.

Does taking siponimod increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. According to the product label, experimental animal studies reported an increased chance for birth defects. Studies have not been done in human pregnancy to see if siponimod increases the chance for birth defects above the background risk.

Does taking siponimod in pregnancy cause other pregnancy-related problems?

According to the product label, experimental animal studies reported a chance of low birth weight. Studies have not been done in human pregnancy to see if siponimod increases the chance for pregnancy-related problems such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

Does taking siponimod in pregnancy affect future behavior or learning for the child?

Studies have not been done to see if siponimod can cause behavior or learning issues for the child.

Breastfeeding while taking siponimod:

Siponimod has not been studied for use while breastfeeding. It is not known if it can enter human breastmilk or how it might affect a nursing child. If you are taking siponimod while breastfeeding and you suspect the baby has any symptoms contact the child’s healthcare provider. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

If a male takes siponimod, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

Studies have not been done to see if siponimod could affect male fertility or increase the chance of birth defects. In
general, exposures that fathers or sperm donors have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

MotherToBaby is currently conducting a study looking at multiple sclerosis and medications used to treat it in pregnancy. If you would like to learn more about this study, please call 1-877-311-8972 or visit https://mothertobaby.org/join-study/.

Please click here for references.