Hydroxyurea (Hydrea®; Siklos®)

This sheet is about exposure to hydroxyurea in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What is hydroxyurea?

Hydroxyurea is a medication that has been used to treat certain blood disorders (sickle cell disease, specific types of blood cancers) and a skin cancer called squamous cell carcinoma. Some brand names for hydroxyurea are Hydrea® and Siklos®.

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 your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

People with sickle cell disease can have healthy pregnancies. Close monitoring by your healthcare team during pregnancy is important. Having sickle cell disease itself can increase the chance of pregnancy complications including the chance of miscarriage, preterm delivery (birth before 37 weeks), low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth), and stillbirth. The chance of health problems that result from being pregnant and giving birth are increased in people with sickle cell disease. If you are planning a pregnancy, see https://www.cdc.gov/ncbddd/sicklecell/materials/women-with-scd-preconception-care.html

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

It is not known if hydroxyurea can make it harder to get pregnant. However, having sickle cell disease may make it harder to get pregnant.

Does taking hydroxyurea increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. In 1 study of people with sickle cell disease who were taking hydroxyurea 1 month before a pregnancy started, when a pregnancy began (conception), and during the pregnancy, a higher chance for miscarriage was noted. However, research also shows that sickle cell disease itself could increase the chance for miscarriage. This makes it hard to know if it is the medication, sickle cell disease or other factors that could increase the chance for miscarriage.

Does taking hydroxyurea 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. In animal studies, hydroxyurea increased the chance of birth defects. Information on the use of hydroxyurea in humans is very limited. There are over 100 human case reports of use of hydroxyurea in pregnancy with no birth defects reported.

Does taking hydroxyurea in pregnancy increase the chance of other pregnancy-related problems?

Preterm delivery, low birth weight, and respiratory distress (trouble breathing) in the baby have been reported after exposure to hydroxyurea during pregnancy. However, sickle cell disease itself can increase risks to a pregnancy. That makes it hard to know if the medication, the condition being treated, or other factors that are related to reported issues.

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

Studies have not been done to see if hydroxyurea increases the chance for behavior or learning issues.

Breastfeeding while taking hydroxyurea:

Hydroxyurea gets into breast milk. There is no information on possible side effects in nursing children who are exposed to hydroxyurea through breastmilk.

An expert panel from the National Institutes of Health and the product labels for hydroxyurea recommend that people who are breastfeeding not use this medication. But the benefits of treating your condition, along with the benefits of
breastfeeding your baby, may outweigh possible risks. Talk with your healthcare providers about the best way to treat your condition while breastfeeding. Be sure to talk to your healthcare provider about all your breastfeeding questions.

**If a male takes hydroxyurea, could it affect fertility or increase the chance of birth defects?**

There have been reports of lowered sperm count (number of sperm) and lowered sperm motility (movement of sperm) in males who take hydroxyurea. This can affect male fertility (ability to get partner pregnant). It is not known if hydroxyurea can increase the chance of birth defects above the background risk when taken by males. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.