# Hydroxyurea (Hydrea®; Siklos®)

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

## *What is hydroxyurea?*

Hydroxyurea is a medication that has been used to treat certain cancers, myeloproliferative disorders, and sickle cell disease. Some brand names for hydroxyurea are Droxia®, Hydrea®, Siklos®, and Xromi®.

Sometimes when women find out they are pregnant, they think about changing how they take their medication or stopping it 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.

The product label for hydroxyurea recommends that women avoid becoming pregnant while using this medication. This is due to animal studies that showed harm to the fetus and concerns about the way the medication works in the body (by interfering with how certain cells work). However, the benefit of using hydroxyurea may outweigh possible risks. Speak with your healthcare provider about using hydroxyurea and what treatment is best for you.

## *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.

## *Does taking hydroxyurea increase the chance of miscarriage?*

Miscarriage is common and can occur in any pregnancy for many different reasons. In a study of 1,788 pregnancies in women with sickle cell disease, a higher rate of miscarriage was reported among those taking hydroxyurea during pregnancy. Taking hydroxyurea only around the time of conception was not linked to an increased risk. Other studies have also reported an increased chance of miscarriage when hydroxyurea is used during pregnancy. However, research also shows that some of the conditions this medication is used to treat can increase the chance of miscarriage. This makes it hard to know if it is the medication, the medical condition being treated, or other factors (such as other health conditions or medications) that could increase the chance of miscarriage.

## *Does taking hydroxyurea increase the chance of birth defects?*

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like hydroxyurea, might increase the chance of birth defects in a pregnancy. It is not known if hydroxyurea can increase the chance of birth defects.

In animal studies, hydroxyurea increased the chance of birth defects; however, animal results do not always predict what will happen in humans. Information on the use of hydroxyurea in humans is limited. There has been one report of a baby born with multiple birth defects after hydroxyurea exposure. No major birth defects were reported among approximately 182 pregnancies with first-trimester exposure. Among an additional 130 first-trimester pregnancies with hydroxyurea exposure, no increase in the chance of birth defects was 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. In a study of 1,788 pregnancies in women with sickle cell disease, a higher rate of stillbirth was reported among those taking hydroxyurea during pregnancy. However, some of the conditions this medication is used to treat can increase risks to a pregnancy. That makes it hard to know if the medication, the condition being treated, or other factors (such as other health conditions or medications) are related to reported pregnancy problems.

### *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 after exposure during pregnancy.

### *Breastfeeding while taking hydroxyurea:*

Hydroxyurea gets into breast milk in small amounts. One study in 16 women found that the amount of hydroxyurea that passes into breast milk is about 3.4% of the mother's dose. Waiting to nurse until about 3 hours after the dose could reduce the infant's exposure by about half. There is no information on possible side effects in nursing children who are exposed to hydroxyurea through breast milk.

The product labels for hydroxyurea and an expert panel from the National Institutes of Health recommend that women who are breastfeeding not use this medication. However, 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 man takes hydroxyurea, could it affect his 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) and absence of sperm in men who take hydroxyurea. This affects male fertility (ability to make healthy sperm). These changes in sperm are sometimes reversible after stopping the medication, but recovery might not always be complete. Men who may want to have children in the future should talk with their healthcare providers about saving sperm (sperm banking) before starting treatment with hydroxyurea. It is important to know that some of the conditions this medication has been used to treat can also cause sperm problems, so it can be hard to know how much is caused by the medication versus the medical condition.

It is not known if hydroxyurea can increase the chance of birth defects above the background risk when taken by men. In general, exposures that men have are less likely 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.



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