Pegvaliase (Palynziq®)

This sheet is about exposure to pegvaliase 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 provider.

What is pegvaliase?

Pegvaliase is a medication that has been used to treat phenylketonuria (PKU), a health condition where a person has higher levels of an amino acid called phenylalanine (Phe). People with PKU do not have the enzyme needed for the body to break down Phe. This can cause harmful buildup, leading to serious health problems. Pegvaliase works by removing excess Phe from a person's body. A brand name for pegvaliase is Palynziq®.

Having PKU that is not well controlled during pregnancy can increase the chance of birth defects and other pregnancy-related problems. MotherToBaby has a fact sheet on PKU here: https://mothertobaby.org/fact-sheets/maternal-pku-pregnancy/.

Sometimes when women 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.

For women with PKU who are pregnant or planning pregnancy, the American College of Obstetricians and Gynecologists (ACOG) recommend keeping phenylalanine (Phe) levels below 6 mg/dL (363 µmol/L) for at least 3 months before pregnancy and between 2–6 mg/dL during pregnancy to lower the chance of birth defects and other problems. The American College of Medical Genetics and Genomics (ACMG) recommends keeping Phe levels below 360 µmol/L before and during pregnancy. It is important to work closely with your healthcare team, including your obstetrician and PKU specialist, before pregnancy if possible, or as soon as you find out you are pregnant, to make a treatment plan for before, during, and after pregnancy.

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

It is not known if taking pegvaliase can make it harder to get pregnant. In animal studies, rats given 19 times the human dose had lower fertility (ability to get pregnant). Rats given 4 times the human dose showed no changes in fertility.

Does taking pegvaliase increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. It is not known if pegvaliase can increase the chance of miscarriage. Some studies have found that having PKU with high levels of Phe can increase the chance of miscarriage.

Does taking pegvaliase 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 pegvaliase, might increase the chance of birth defects in a pregnancy.

It is not known if pegvaliase can increase the chance of birth defects. In one small study of 16 children exposed to pegvaliase during pregnancy, no birth defects were reported.

Women with PKU who are pregnant and who have high levels of Phe have a higher chance of having a baby with a very small head (microcephaly) and heart defects.

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

It is not known if pegvaliase can increase the chance of other 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).

In one small study of 16 children exposed to pegvaliase during pregnancy, a higher number was born preterm than expected. However, more research is needed to know whether pegvaliase itself, PKU, or other factors increase the chance of preterm delivery. It is also important to keep phenylalanine (Phe) levels in a healthy range during pregnancy, as high Phe levels are linked to babies being born smaller than expected.

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

It is not known if pegvaliase can increase the chance for behavior or learning issues for the child.

Having high levels of Phe in pregnancy can increase the chance of a child having intellectual disability, behavior issues, and seizures.

Breastfeeding while taking pegvaliase:

Pegvaliase passes into breast milk in very small amounts. In 2 infants exposed to pegvaliase through breast milk, no side effects were reported. Experts from the Genetic Metabolic Dietitians International (GMDI) and Southeast Regional Genetics Network (SERN) support the use of pegvaliase in breastfeeding. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes pegvaliase, could it affect fertility or increase the chance of birth defects?

It is not known if pegvaliase could increase the chance of birth defects. One study reported lower amounts of sperm in men with PKU, which can affect men's fertility (ability to make healthy sperm). 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.

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