Leflunomide (Arava®)

This sheet is about exposure to leflunomide 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 leflunomide?

Leflunomide is a medication that has been used to treat rheumatoid arthritis. It is in the class of medications known as DMARDs (disease modifying anti-rheumatic drugs). Leflunomide can reduce arthritis symptoms and slow down joint damage. A brand name of leflunomide is Arava®.

The product label for leflunomide recommends that women who are pregnant or trying to get pregnant not use this medication. However, the benefit of using leflunomide may outweigh possible risks. Your healthcare provider can talk with you about using leflunomide and what treatment is best for you.

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

People eliminate medication at different rates. In healthy adults, it takes about 10 weeks (2 and 1/2 months), on average, for most of the leflunomide to be gone from the body. However, the manufacturer of Arava® says that for some people it could take up to 2 years for the drug to completely leave the body. Talk with your healthcare providers about checking your blood levels of leflunomide and, if needed, what treatments are available to help remove the medication from your body faster (washout treatment).

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

It is not known if leflunomide can make it harder to get pregnant.

Does taking leflunomide increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Small studies and case reports of women who became pregnant while taking leflunomide have not suggested an increased chance of miscarriage.

Does taking leflunomide 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. Animal studies have suggested that leflunomide can increase the chance of birth defects.

Case reports and studies on leflunomide exposure in human pregnancy have not found an increased chance of birth defects. Most women in these studies and reports stopped taking leflunomide very early in pregnancy once they found out they were pregnant and received washout treatment to remove the medication from the body more quickly. It is hard to know from these studies and reports how longer exposure to leflunomide may affect a pregnancy. Case reports and two small studies of women with longer exposures to leflunomide in pregnancy have not suggested an increased chance of birth defects.

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

Limited information about the use of leflunomide later in pregnancy does not suggest an increased 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).

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

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

Breastfeeding while taking leflunomide:

Studies have not been done on the use of leflunomide in breastfeeding. Leflunomide stays in the body for a long time, which means it could build up in the breast milk in higher amounts over time. Since leflunomide can weaken the

immune system of adults who take it, there is concern that amounts of this medication in the milk might affect the immune system of a nursing child.

The product label for leflunomide recommends women who are breastfeeding not use this medication. Your healthcare providers can talk with you about using leflunomide and what treatment is best for you. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Studies have not been done to see if leflunomide could affect a man's fertility (ability to get a woman pregnant). One study that included a small number of men who received prescriptions for leflunomide to treat rheumatoid arthritis did not find an increased chance of birth defects. In general, exposures that men 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.

MotherToBaby is currently conducting a study looking at leflunomide and other medications used to treat rheumatoid arthritis in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972 or sign up at https://mothertobaby.org/join-study/.

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