Leflunomide (Arava®)

This sheet is about exposure to leflunomide 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 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®.

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.

The product label for leflunomide and multiple professional guidelines recommend that women who are pregnant or trying to get pregnant not use this medication. This is because there is not enough information available on the use of leflunomide to know if/how it could affect a pregnancy. However, the benefit of using leflunomide might 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 becoming pregnant. How long does the drug stay in my body?

The time it takes the body to metabolize (to process) medication is not the same for everyone. In healthy non-pregnant 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 to your healthcare providers about checking your blood levels of leflunomide. They can also tell you 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. One study reported a slightly increased chance for miscarriage when leflunomide was used in the 3 months before pregnancy. This study had limitations that make it hard to know if the increased chance of miscarriage was caused by leflunomide or other factors. There are other small studies and case reports of women who became pregnant while taking leflunomide. They did not suggest an increased chance of miscarriage. As there can be many causes of miscarriage, it is hard to know if a medication, the medical condition being treated, or other factors (such as age, health, other exposures) are the cause of a miscarriage.

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

Animal studies have suggested that leflunomide can increase the chance of birth defects. A few reports in humans have also described birth defects in a small number of pregnancies exposed to leflunomide. In addition, one small study reported a higher rate of birth defects. However, this study had limitations that makes it hard to know if the reported findings were related to leflunomide or other factors.

Other reports and studies on leflunomide exposure in human pregnancy have not found an increased chance of birth defects. In most cases, the women stopped taking leflunomide very early in pregnancy once they found out they were pregnant. They also received treatment to remove the medication from their bodies more quickly. Because of this, it is

hard to know from these studies and reports how longer exposures to leflunomide might affect a pregnancy. However, there are case reports and 2 small studies of women with longer exposures to leflunomide in pregnancy. These 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 increase the chance of 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. Leflunomide can weaken the immune system of people who take it. Because of this, there is concern that if this medication passes into breast milk, it might affect the immune system of a nursing child.

The product label for leflunomide and multiple professional guidelines recommend that women who are breastfeeding not use this medication. This is because there is not enough information available on the use of leflunomide to know if/how it could affect a breastfed baby. But the benefits of using leflunomide and breastfeeding might outweigh possible risks. 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 his fertility or increase the chance of birth defects?

Studies have not been done to see if leflunomide could affect male fertility (ability to make healthy sperm). One study that included a small number of males who received prescriptions for leflunomide to treat rheumatoid arthritis did not find an increased chance of birth defects. Experts do not agree on whether men should stop taking leflunomide before trying to have a baby. 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.

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