



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Leflunomide (Arava®)

This sheet talks about the risks that exposure to leflunomide can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. This information should not take the place of medical care and advice from your health care provider.

What is leflunomide?

Leflunomide is a prescription medication used to treat the autoimmune condition rheumatoid arthritis. Leflunomide is a medication that decreases inflammation (swelling). It is classified as a DMARD (disease modifying anti-rheumatic drug) because it can reduce arthritis symptoms like joint swelling and can slow down joint damage. Leflunomide is available as a generic drug or sold under the brand name Arava®.

Should I stop taking it before I try to get pregnant? How long does leflunomide stay in the body?

The manufacturer recommends that women should NOT take leflunomide if they are trying to get pregnant, if they are not actively using birth control to prevent a pregnancy, or if they are already pregnant. However, you should not stop taking any medications without first talking with your health care provider.

Individuals break down medicines at different rates. On average, it takes about 10 weeks (two and a half months) after the last leflunomide dose for most of the medicine to be gone from the body. However, the manufacturer of Arava® says that for some people it could take up to two years for all of the medicine to leave the body. Treatments (like cholestyramine or charcoal) can be given to help shorten the time it takes for leflunomide to leave the body. Cholestyramine or charcoal, when taken as prescribed, can help remove leflunomide from the body, usually within two weeks.

If you are a woman who wants to become pregnant, it is recommended that you start trying to get pregnant only AFTER a blood test shows leflunomide is completely out of your blood. If a blood test shows that levels of the medication are still in your blood, there are treatments to help clear the leflunomide from your blood more quickly, such as cholestyramine or charcoal. If leflunomide is still found in the blood after one or more courses of treatment with cholestyramine or charcoal, the process may need to be repeated. To be sure leflunomide is out of your blood before pregnancy, the cholestyramine or charcoal treatments should be completed and a blood level should show that the medication is out of your system before trying to get pregnant. Your health care provider can help you get the blood test to check leflunomide levels and can help you with treatments to remove the drug from your body. One group of authors state that based on the data a waiting period of 3.5 months before trying to get pregnant should be enough time.

Can taking leflunomide make it more difficult for me to become pregnant or increase the chance of miscarriage?

Animal studies done by the manufacturer did not find that leflunomide made it more difficult to get pregnant. However, women who are trying to get pregnant should not be taking leflunomide.

For women who accidentally become pregnant while on leflunomide, the results from human data has not suggested an increased chance of miscarriage.

Can taking leflunomide during my pregnancy cause birth defects?

It is not known whether leflunomide increases the chance of birth defects in humans because the number of exposed pregnancies remains small. Concern has been raised about leflunomide because pregnancy studies in animals showed an increased chance of birth defects when treated with the medication at levels comparable to those used to treat humans.

Results from case reports, registries and studies have not shown an increased chance of birth defects or a

distinct pattern of birth defects common to infants that were exposed to leflunomide during pregnancy. One small study of 109 women (64 women in the main study and 45 in the case-series study) who became pregnant while taking leflunomide did not find an increased chance of birth defects. Although this study is reassuring, nearly all of the women in the study stopped taking leflunomide very early in their pregnancy, and, received the recommended cholestyramine treatment once they found out that they were pregnant, which eliminated the drug as quickly as possible from their blood. These factors make it more difficult to draw conclusions about the possible effects leflunomide might have on pregnancies where women had leflunomide in their blood for longer periods of time in pregnancy. Two small studies where some of the women did not receive the recommended ‘wash out’ treatment with cholestyramine, and were exposed during the first trimester, did not suggest an increased chance of birth defects.

These studies give some reassurance for pregnancies that unintentionally occur while the mother is taking leflunomide. However, larger studies are needed to determine safety of use during pregnancy. Until these larger and longer-term studies are done, avoiding leflunomide during pregnancy is recommended.

Can taking leflunomide cause pregnancy complications?

The limited data from a few studies has not supported an increased chance of prematurity (birth before 37 weeks), or low birth weight (less than 5 lbs., 8 oz.) with the use of leflunomide during pregnancy.

Can I take leflunomide while breastfeeding?

Leflunomide is not recommended during breastfeeding. First, there is no information on the amount of leflunomide that can get into the breastmilk. Secondly, medications with a long-half life (the amount of time for 50% of the drug to eliminate from the body), such as leflunomide, have the potential to build up in the breast milk. Also, in persons who take leflunomide, the medication has the ability to weaken the immune system, which leads to some concerns about the potential effects to the infant. Finally, there are no studies looking at the use of leflunomide in breastfeeding. Talk to your healthcare provider about all of your breastfeeding questions.

What if the father of the baby takes leflunomide?

There was one study that observed men who received prescriptions for medications used to treat rheumatoid arthritis. A small number of these expectant fathers were exposed to leflunomide three months prior to pregnancy. While the data is quite limited regarding leflunomide specifically, no increased chance of birth defects were observed. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby is currently conducting a study looking at rheumatoid arthritis and the medications used to treat RA in pregnancy. If you would like to learn more, please call 1-877-311-8972 or visit <https://mothertobaby.org/join-study/>.

Please click [here](#) for references.

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