



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

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Teriflunomide (Aubagio®)

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to teriflunomide may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is teriflunomide?

Teriflunomide is a prescription medication used to treat multiple sclerosis. It is a pill taken by mouth, typically once per day. It is marketed under the brand name Aubagio®. There is another medication, called leflunomide, which turns into teriflunomide in the body. For more information on this similar medication, please see the fact sheet Leflunomide and Pregnancy at <https://mothertobaby.org/fact-sheets/leflunomide-pregnancy/pdf/>.

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

Until more information becomes available through studies, the manufacturer recommended that women should not take teriflunomide if: 1) they are trying to get pregnant, 2) are not actively avoiding pregnancy (such as by using birth control pills or condoms), or 3) are already pregnant. However, you should talk with your health care provider before stopping any of your prescription medications.

Individuals break down medicines at different rates. On average most of this medication should be gone from the body of non-pregnant adults about four months after stopping. However, not everyone is the same and it could take up to two years from some people to clear this medication from their body. There are treatments to help the body clear this medicine faster, if needed. These can be discussed with your health care provider if there is a concern for you.

If you are trying to become pregnant, it is recommended that you wait to get pregnant until AFTER a blood test shows teriflunomide is completely out of your blood. If a blood test shows that levels of the medication are still in your blood, there are treatments, such as cholestyramine or charcoal, to help clear teriflunomide from your body. If teriflunomide is still found in the blood after treatment with cholestyramine or charcoal, the process may need to be repeated. Your health care provider can prescribe treatments to remove teriflunomide from your body and help you get the blood test for teriflunomide levels in your blood.

Can taking teriflunomide make it more difficult for me to become pregnant?

It is not known if teriflunomide can make it more difficult to get pregnant. However, women who are trying to get pregnant are not recommended to take teriflunomide. If you are trying to become pregnant and are on teriflunomide it is important for you to talk with your health care provider.

Can taking teriflunomide during my pregnancy cause birth defects?

It is not known whether teriflunomide increases the chance for birth defects in humans. Studies in animals show an increased chance of birth defects with exposure to teriflunomide.

There were 12 pregnancies reported to have normal deliveries (normal birth weights and no birth defects) during clinical trials for teriflunomide. These women underwent the elimination procedure described in this fact sheet. In 2014, the manufacturer also reported on 83 pregnancies reported in their database. All newborns were healthy and did not have any birth defects at delivery. A small study on 109 women who became pregnant while taking leflunomide (a related medicine) did not find an increased risk of birth defects. Although reassuring, nearly all of the women in the studies stopped taking leflunomide very early in their pregnancy (around 5 weeks gestation). Most of these women took the recommended cholestyramine treatment once they found out they were pregnant, and cleared the drug as quickly as

possible from their blood. These factors make it difficult to draw conclusions about the possible effects teriflunomide might have on pregnancies.

Larger studies are needed to determine safety of use of teriflunomide during pregnancy. Until larger and longer term studies are done, it is best to avoid teriflunomide during pregnancy. If teriflunomide is taken during pregnancy, elimination of the medication can be discussed with your health care provider.

Can I take teriflunomide while breastfeeding?

There are no studies looking at the use of teriflunomide in breastfeeding. Because there is a lack of information, and the medicine has the ability to suppress the immune system, teriflunomide is not recommended while breastfeeding.

What if the father of the baby takes teriflunomide?

Limited information is available on the outcomes of pregnancies fathered by a man taking teriflunomide. The manufacturer recommends that the elimination procedure be used by men planning on fathering a baby.

In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet on Paternal Exposures and Pregnancy at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby is currently conducting a study looking at teriflunomide 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/>.

References Available Upon Request

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