

Teriflunomide (Aubagio®)

This sheet is about exposure to teriflunomide in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare providers.

What is teriflunomide?

Teriflunomide is a prescription medication used to treat multiple sclerosis (MS). 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 at <https://mothertobaby.org/fact-sheets/leflunomide-pregnancy/>.

The product label for teriflunomide recommends people should NOT take teriflunomide 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 healthcare provider. Your healthcare providers can talk with you about using teriflunomide and what treatment is best for you.

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

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

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

People eliminate medication at different rates. In healthy adults, it takes up to four months after stopping teriflunomide for most of the teriflunomide to be gone from the body. However, not everyone is the same and it could take up to 2 years for some people to clear this medication from their body. There are treatments to help the body clear this medication faster. These can be discussed with your healthcare provider if there is a concern for you. If you are trying to become pregnant, it has been recommended that you wait to get pregnant until AFTER a blood test shows teriflunomide is completely out of your blood.

Does taking teriflunomide increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Based on the studies reviewed, it is not known if teriflunomide increases the chance for miscarriage. However, according to the product labeling there was no increase in miscarriage in 150 pregnancies with teriflunomide exposure early in the 1st trimester and use of the rapid elimination procedure.

Does taking teriflunomide 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. Experimental animal studies show an increased chance of birth defects with exposure to teriflunomide.

In humans it is not fully understood whether teriflunomide increases the chance for birth defects. This is because there are case reports where babies exposed to teriflunomide during pregnancy had birth defects. However, there are also case reports of babies born healthy and without birth defects with exposure to teriflunomide during pregnancy. In many cases the pregnant person underwent the accelerated (rapid) elimination procedure which would have reduced the teriflunomide exposure to the baby.

A paper summarizing clinical studies through December of 2017 described 222 pregnancies. Among these, 4 birth defects were reported (3.6%, which is similar to the background risk of birth defects) and no pattern was seen in those birth defects. Many of these people took the recommended elimination treatment once they found out they were pregnant to remove the drug as quickly as possible from their blood.

A 2020 study of 47 pregnancies exposed to teriflunomide during all three trimesters (with 23 live-born infants) did not find an increased chance of birth defects. Until larger and longer-term studies are done, it has been recommended to avoid teriflunomide during pregnancy. If teriflunomide is taken during pregnancy, rapid elimination of the medication

can be discussed with your healthcare provider.

Does taking teriflunomide increase the chance of other pregnancy problems?

Based on the studies reviewed, it is not known if teriflunomide can cause 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 teriflunomide in pregnancy affect future behavior or learning for the child?

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

Breastfeeding while taking teriflunomide:

There are no studies looking at the use of teriflunomide in breastfeeding. Because there is a lack of information, and the medication has the ability to suppress the immune system, the product label for teriflunomide recommends people who are breastfeeding not use this medication. But, the benefit of using teriflunomide may outweigh possible risks. Your healthcare providers can talk with you about using teriflunomide and what treatment is best for you. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

If a male takes teriflunomide, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

Very little information is available on the outcomes of pregnancies if semen was exposed to teriflunomide. There is 1 study among 18 males who received teriflunomide an average of 198 days leading up to conception in their partner. All pregnancies in their partners resulted in live births, with only one report of a malformation (plagiocephaly, also called “flat head syndrome” because of the way it affects the shape of a baby’s head). Teriflunomide is found in semen. The manufacturer recommends that males and their partners should use reliable contraception during therapy. The rapid elimination procedure should be used in males who are planning to conceive; or they should wait to try to get a partner pregnant until after their blood levels of teriflunomide are low. For general information on exposures that males might have, please see the MotherToBaby fact sheet called Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

MotherToBaby is currently conducting a study looking at multiple sclerosis and the medications used to treat MS in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972 or visit <https://mothertobaby.org/join-study/>.

Please click here for references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://mothertobaby.org).

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). *OTIS/MotherToBaby encourages inclusive and person-centered language. While our name still contains a reference to mothers, we are updating our resources with more inclusive terms. Use of the term mother or maternal refers to a person who is pregnant. Use of the term father or paternal refers to a person who contributes sperm.* Copyright by OTIS, December 1, 2022.