# Teriflunomide (Aubagio®)

This sheet is about exposure to teriflunomide 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 teriflunomide?*

Teriflunomide is a prescription medication that has been 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 women 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.

The drug label also states that after stopping teriflunomide, all women of childbearing potential should receive a treatment to help eliminate the drug faster from the body (called a “washout”). Women planning pregnancy are also recommended to stop teriflunomide and receive a treatment to eliminate the drug from the body faster. After receiving treatment to wash out the medication, the drug label states that women should not try and get pregnant until levels of teriflunomide in blood are less than 0.02 mg/L (0.02 mcg/mL).

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

It is not known if teriflunomide can make it harder to get pregnant. It is recommended that women who are trying to get pregnant not take teriflunomide. If you are trying to get 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 getting 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 up to four months after stopping teriflunomide for most of the medication to be gone from the body. 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. Talk with your healthcare provider if there is a concern for you.

## *Does taking teriflunomide increase the chance of miscarriage?*

Miscarriage is common and can occur in any pregnancy for many different reasons. It is not known if teriflunomide can increase the chance of miscarriage. No increase in miscarriage was reported in 150 pregnancies with teriflunomide exposure early in the 1st trimester and use of the rapid washout procedure.

## *Does taking teriflunomide 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 published data to try to understand if an exposure, like teriflunomide, might increase the chance of birth defects in a pregnancy.

It is unknown if taking teriflunomide in pregnancy can increase the chance of birth defects. Reports looking at a total of over 250 pregnancies with exposure to teriflunomide did not find an increased chance of birth defects. It has been recommended to avoid teriflunomide during pregnancy. If teriflunomide is taken during pregnancy, talk with your healthcare provider about rapid washout of the medication.

## *Does taking teriflunomide increase the chance of other pregnancy-related problems?*

Studies have not been done to see if teriflunomide can increase the 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 teriflunomide in pregnancy affect future behavior or learning for the child?*

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

### *Breastfeeding while taking teriflunomide:*

There are no studies looking at the use of teriflunomide in breastfeeding. It is unknown how much of the medication can get into breast milk. The product label for teriflunomide recommends women who are breastfeeding not use this medication. 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 your breastfeeding questions.

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

It is not known if taking teriflunomide can affect men's fertility (ability to get a woman pregnant). One study looked at 18 males who received teriflunomide an average of 198 days leading up to conception in their partner. All pregnancies resulted in live births, with only one report of a birth defect (plagiocephaly). The manufacturer recommends that men and their partners use reliable contraception while taking this medication. Men who are planning to conceive should talk with their healthcare provides about the rapid washout or waiting to try to get a woman pregnant until after his blood levels of teriflunomide are low. For general information on exposures that men might have, please see the MotherToBaby fact sheet 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.**



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