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. 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/.

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, people 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 healthcare provider.

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

Until more information becomes available through studies, the product label for teriflunomide recommends that people who are pregnant or breastfeeding 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 healthcare provider before stopping your prescription medications.

People eliminate medication at different rates. In healthy adults, it takes up to four months after stopping 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, if needed. 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 can occur in any pregnancy. Based on the data available, it is not known if teriflunomide increases the chance for miscarriage.

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. It is not known whether teriflunomide increases the chance for birth defects in humans. Studies in animals show an increased chance of birth defects. Although reassuring, nearly all of the people in the studies stopped taking leflunomide very early in their pregnancy (around 5 weeks gestation). Most 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. These factors make it difficult to draw conclusions about the possible effects teriflunomide might have on pregnancies.

There were 12 pregnancies reported to have normal deliveries (normal birth weights and no birth defects) during clinical trials for teriflunomide. These people underwent an elimination procedure. In 2014, the manufacturer reported on 83 pregnancies from their database. All newborns were healthy and did not have any birth defects at delivery. A small study on 109 people who became pregnant while taking leflunomide (a related medication) did not find an increased chance of birth defects. Although reassuring, nearly all of the people in the studies stopped taking leflunomide very early in their pregnancy (around 5 weeks gestation). Most 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. These factors make it difficult to draw conclusions about the possible effects teriflunomide might have on pregnancies.

A 2017 study of 65 pregnancies exposed to teriflunomide early in the first trimester, with 39 infants born, did not find and increased chance of birth defects. A 2020 study of 47 pregnancies exposed to teriflunomide during all three trimesters, with 23 infants born, did not find an increased chance of birth defects. Larger scientific studies are needed to learn more about the use of teriflunomide during pregnancy. Until larger and longer term studies are done, has
been recommended to avoid teriflunomide during pregnancy. If teriflunomide is taken during pregnancy, elimination of the medication can be discussed with your healthcare provider.

**Could taking teriflunomide cause other pregnancy problems?**

Based on the available data, it is not known if teriflunomide can cause other pregnancy complications.

**Does taking teriflunomide in pregnancy cause long-term problems in behavior for the baby?**

Based on the available data, it is not known if teriflunomide can cause behavior or learning issues.

**Can I breastfeed 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, teriflunomide has not recommended while breastfeeding. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

**I take teriflunomide. Can it make it harder for me to get my 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. One small study on 18 men treated with teriflunomide 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). However, normal vaginal delivery can commonly misshape a baby’s head as the baby passes through the birth canal. Until more information is available, the manufacturer recommends the elimination procedure be used in people who are trying to conceive. For more information, please see the MotherToBaby fact sheet 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.