

Natalizumab (Tysabri®)

This sheet is about exposure to natalizumab in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What is natalizumab?

Natalizumab is a monoclonal antibody given by injection (shot). It is designed to target the $\alpha 4$ integrin protein on white blood cells to reduce swelling and damage to nerves. Natalizumab has been used to treat severe multiple sclerosis (MS) or Crohn's disease when other medications have not worked. Natalizumab is sold under the brand name Tysabri®.

Sometimes when women find out they are pregnant, they think about changing how they take their medication or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

MotherToBaby has a fact sheet on MS here <https://mothertobaby.org/fact-sheets/multiple-sclerosis/> and inflammatory bowel disease (including Crohn's disease) here:

<https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/>.

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

The time it takes to break down (metabolize) medication is not the same for everyone. In healthy adults, it takes up to 2 months, on average, for most of the natalizumab to be gone from the body.

Some sources recommend stopping natalizumab in pregnancy while others do not. Available information shows a high chance of a return of symptoms (relapse) when natalizumab is stopped before pregnancy. It is important that you talk with your healthcare providers about your treatment options before pregnancy, or as soon as you learn that you are pregnant. They can go over the best way to treat your condition before, during, and after pregnancy.

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

Studies have not been done in women to see if natalizumab can make it harder to get pregnant.

Does taking natalizumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Information on over 500 pregnancies does not suggest an increased chance of miscarriage.

Does taking natalizumab 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. Information on over 500 pregnancies that were exposed to natalizumab does not suggest an increased chance of birth defects.

Natalizumab, like other monoclonal antibodies, crosses the placenta at the end of the first 3 months of pregnancy. This limits the exposure to the fetus during the early pregnancy. The transfer of natalizumab is increased for the rest of the pregnancy.

Does taking natalizumab in pregnancy increase the chance of other pregnancy-related problems?

One study looking at over 1000 pregnancies compared the rates of preterm delivery (birth before week 37), being small for gestational age (fetus is smaller than the usual based on the number of weeks of pregnancy), stillbirth, and Apgar scores (a test that is used to evaluate the health of a newborn baby immediately after birth) to women on similar medications and to the general public. The rates of these issues were similar for all the groups. Women on natalizumab or a similar medication during pregnancy had higher rates of C-sections compared to the general public.

Studies have reported blood conditions such as thrombocytopenia (low number of platelets, which help blood clot) and anemia (low amount of red blood cells) in infants exposed to natalizumab in the third trimester of pregnancy. The

conditions were mild, did not require any special treatment, and went away on their own within 4 months. Not all babies exposed to natalizumab will have these issues. It is important that your healthcare providers know you are taking natalizumab so your baby can be monitored for these conditions after delivery, if needed.

Does taking natalizumab in pregnancy affect future behavior or learning for the child?

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

Breastfeeding while taking natalizumab:

Limited information suggests natalizumab gets into breastmilk in small amounts in some women. Natalizumab is a large protein molecule and is unlikely to be absorbed by the infant in large amounts. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

One small study compared 16 men who had severe MS and were taking natalizumab for treatment to 16 other men who were not taking natalizumab. Over 12 months, no difference in fertility (ability to get a woman pregnant) was reported between the two groups. For some men, the underlying condition being treated can increase the chance of sexual dysfunction or lower quality of sperm, which can affect a man's fertility. In general, exposures that men have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

Please click here to view references.

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

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