Natalizumab (Tysabri®)

This sheet is about exposure to natalizumab 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 natalizumab?

Natalizumab is a monoclonal antibody given by injection (shot). 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. Available information suggests that stopping natalizumab before pregnancy may increase the chance of a return of symptoms (relapse), while continuing treatment during pregnancy was associated with fewer relapses and lower recurrence rates. 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.

MotherToBaby has fact sheets on MS https://mothertobaby.org/fact-sheets/multiple-sclerosis/ and inflammatory bowel disease (including Crohn's disease) 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 the body to metabolize (process) medication is not the same for everyone. In healthy non-pregnant adults, it could take up to 70 days (a little over 2 months), on average, for most of the natalizumab to be gone from the body.

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

Studies have not been done in humans 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?

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 research studies to try to understand if an exposure, like natalizumab, might increase the chance of birth defects in a pregnancy. Data on the use of natalizumab in pregnancy is limited. Most available information 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 overall exposure to the fetus. The transfer of natalizumab increases for the rest of the pregnancy.

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

Some studies found that natalizumab exposure during pregnancy, especially in the third trimester, was associated with lower infant birth weight and shorter length at birth. Most studies did not find an increased chance of preterm birth (before 37 weeks), stillbirth, placental complications, or poor newborn outcomes compared with unexposed pregnancies, other MS treatments, or the general population. Higher rates of C-section were reported in women using natalizumab or similar medications during pregnancy.

Studies have reported mild blood disorders in infants exposed to natalizumab during the third trimester, including thrombocytopenia (low number of platelets, which help the blood clot) and anemia (low amount of red blood

cells). These conditions did not require treatment and went away on their own within 4 months. One case of neonatal pancytopenia, where all major blood cell types are low, was also reported after exposure to natalizumab throughout pregnancy; it resolved without treatment. 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 on natalizumab use during pregnancy and possible effects on learning and behavior are limited. Available studies found no increased chance of autism, developmental delays, learning problems, behavioral, or psychiatric issues in children exposed during pregnancy. In most pregnancies, children showed normal motor and language development up to 7 years of age. Although one child was diagnosed with autism spectrum disorder and some children had mild behavioral or sleep problems, these were not linked to natalizumab exposure during pregnancy.

Breastfeeding while taking natalizumab:

Limited information suggests small amounts of natalizumab pass into breast milk in some women, mainly in the first week after a dose. It has not been detected in the blood of breastfed infants. Because natalizumab is a large protein, it is unlikely to be absorbed in large amounts by the baby when swallowed. Most experts consider breastfeeding while on natalizumab acceptable. Waiting about 2 weeks after delivery before restarting treatment may further lower infant exposure. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes natalizumab, could it affect his 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 make healthy sperm) 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 fertility. In general, exposures that men have are unlikely to increase 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 for references.

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