Dimethyl Fumarate (Tecfidera®)

This sheet talks about exposure to dimethyl fumarate in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

**What is dimethyl fumarate?**

Dimethyl fumarate is a prescription medication used to treat a type of multiple sclerosis with symptoms that flare up from time to time known as relapsing-remitting multiple sclerosis. Dimethyl fumarate is sometime abbreviated as “DMF and is sold under the brand name Tecfidera®. It works by decreasing inflammation and preventing the nerve damage that causes symptoms of multiple sclerosis. Dimethyl fumarate is also sometimes used to treat plaque psoriasis.


**I take dimethyl fumarate. Can it make it harder for me to get pregnant?**

Studies on women have not been done to see if dimethyl fumarate could make it harder for a woman to get pregnant. Animal studies did not find an effect on female fertility.

**I just found out I am pregnant. Should I stop taking dimethyl fumarate?**

You should talk to your healthcare provider(s) before you or change how you take this medication. The benefits of taking dimethyl fumarate and treating your condition during pregnancy need to be weighed against the possible risks of continuing this medication during pregnancy.

**Does taking dimethyl fumarate increase the chance for miscarriage?**

Miscarriage can occur in any pregnancy. Based on available limited research, it is unlikely that dimethyl fumarate would increase the chance for a miscarriage. In the few reported cases of pregnancies exposed to dimethyl fumarate, the rate of miscarriage was similar to what is seen in the general population.

**Does taking dimethyl fumarate in the first trimester increase the chance of birth defects?**

In every pregnancy, a woman starts out with a 3% to 5% chance of having a baby with a birth defect. This is called her background risk. Dimethyl fumarate has not been well studied for use during a pregnancy. There are published data on 39 pregnancies and their outcomes with exposure to dimethyl fumarate. In this very small group of pregnancies, a higher rate of birth defects or stillbirth was not reported.

**Could taking dimethyl fumarate in the second or third trimester cause other pregnancy complications?**

In the limited number of reported exposed pregnancies who took the medication throughout the entire pregnancy there have been no reports of any pregnancy complications.

**Does taking dimethyl fumarate in pregnancy cause long-term problems in behavior or learning for the baby?**

Given the small number of known exposed human babies, there is not enough information to answer this question. There is currently a pregnancy registry set up to track and monitor the pregnancies and outcomes of children exposed to dimethyl fumarate. For more information on the pregnancy registry, please see: [https://clinicaltrials.gov/ct2/show/NCT01911767?term=NCT01911767&rank=1](https://clinicaltrials.gov/ct2/show/NCT01911767?term=NCT01911767&rank=1)

In animal studies of dimethyl fumarate there was no difference in the learning or behavior performance of exposed animals compared to non-exposed animals.

**Can I take dimethyl fumarate while I am breastfeeding?**

There currently are no information regarding the use of dimethyl fumarate while breastfeeding. Because dimethyl
Dimethyl fumarate (Tecfidera®) is eliminated from the body quickly, it is recommended that women who choose to breastfeed while using this medication consider waiting 4-5 hours after their dose to breast feed to reduce the amount of medication the baby could receive. If you suspect that your baby is not doing well if you take dimethyl fumarate while breastfeeding, contact your child’s healthcare provider. Talk to your healthcare provider about all of your breastfeeding questions.

If a man takes dimethyl fumarate, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?

There are no studies looking at possible risks to a pregnancy when the father takes dimethyl fumarate. In animal studies at low and moderate doses, there was no impact in male fertility. However at very high doses in male rats, there was a decrease in sperm motility after the drug was given. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet on paternal exposures at https://mothertobaby.org/fact-sheets/paternal-exposurespregnancy/pdf/.

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

Selected References:

- Tecfidera prescribing information, available online at: https://www.tecfiderahcp.com/content/dam/commercial/multiple-sclerosis/tecfidera/hcp/en_us/pdf/Tecfidera_PI.pdf, accessed May 2019