Dimethyl Fumarate

This sheet is 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”. It is sold under the brand name Tecfidera®. It works by lowering inflammation and preventing the nerve damage that causes symptoms of multiple sclerosis. Dimethyl fumarate is also sometimes used to treat plaque psoriasis.


Sometimes when people 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 this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

**I take dimethyl fumarate. Can it make it harder for me to get pregnant?**
Based on the studies reviewed, it is not known if dimethyl fumarate could make it harder to get pregnant. Animal studies did not find an effect on female fertility.

**Does taking dimethyl fumarate increase the chance for miscarriage?**
Miscarriage can occur in any pregnancy. Based on the studies reviewed, it is unlikely that dimethyl fumarate would increase the chance for 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 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. Dimethyl fumarate has not been well studied for use during 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 was not reported.

**Does taking dimethyl fumarate in pregnancy increase the chance of other pregnancy-related problems?**
Based on the studies reviewed, it is not known if dimethyl fumarate can cause 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 dimethyl fumarate in pregnancy affect future behavior or learning for the child?**
Based on the studies reviewed, it is not known if dimethyl fumarate increases the chance for behavior or learning issues.

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

**Breastfeeding while taking dimethyl fumarate:**
Dimethyl fumarate enters breast milk in small amounts. Because dimethyl fumarate is eliminated from the body quickly, it is recommended that people 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 the baby has any symptoms such as flushing, vomiting, or diarrhea, contact the child’s healthcare provider. Be sure to talk
to your healthcare provider about all of your breastfeeding questions.

**I take dimethyl fumarate. Can it make it harder for me to get my partner pregnant or increase the chance of birth defects?**

Studies have not been done to see if dimethyl fumarate could affect male fertility or increase the chance of birth defects in humans. In animal studies at low and moderate doses, there was no impact on male fertility. At very high doses in male rats, there was a decrease in sperm motility (the sperm’s ability to move) after the drug was given. In general, exposures that fathers or sperm donors have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet on paternal exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

*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.tecfinderahcp.com/content/dam/commercial/multiple-sclerosis/tecfidera/hcp/en_us/pdf/Tecfidera_PI.pdf.

*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*