Sulfasalazine (Azulfidine®)

This sheet is about exposure to sulfasalazine 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 sulfasalazine?

Sulfasalazine is a medication that has been used to treat inflammatory bowel disease (IBD) and rheumatoid arthritis (RA). A brand name for sulfasalazine is Azulfidine®.

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.

Having IBD or RA that is untreated or not well treated in pregnancy can lower the chance of getting pregnant and can increase the chance of pregnancy complications. MotherToBaby has a fact sheet on IBD here: https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/ and on RA here: https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/.

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

It is not known if sulfasalazine can make it harder to get pregnant. One study looked at women with RA who were taking sulfasalazine before getting pregnant. It did not take longer for them to get pregnant compared to women with RA who were not taking sulfasalazine.

Does taking sulfasalazine increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. No increased chance of miscarriage was reported in one study of 531 women taking sulfasalazine during pregnancy.

Does taking sulfasalazine 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 sulfasalazine, might increase the chance of birth defects in a pregnancy. In studies with over 950 women taking sulfasalazine alone or with other medications during pregnancy, no increased chance of birth defects was reported.

One study reported an association between heart defects and cleft lip and/or palate (an opening in the upper lip or the roof of the mouth) when sulfasalazine or similar medications were taken during pregnancy. However, this study did not look at the underlying health condition being treated, such as RA or IBD, or other health conditions. This makes it hard to know if the sulfasalazine, the underlying condition being treated, or other factors are related to the possible increased chance.

Sulfasalazine can affect folic acid levels in the body. Folic acid is recommended for all women who could become pregnant. It is important to talk with your healthcare provider about how much folic acid is right for you. MotherToBaby has a fact sheet on folic acid here: https://mothertobaby.org/fact-sheets/folic-acid/.

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

It is not known if sulfasalazine can increase the chance of 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).

There was a theoretical (not proven) concern that taking sulfasalazine during pregnancy might increase bilirubin (chemical made in the body after the body breaks down blood cells) levels in the newborn, which could lead to jaundice (yellowing of the skin and eyes) or kernicterus (damage to the brain because of high bilirubin levels). However, in studies with more than 1800 newborns who were exposed to sulfasalazine or similar medications during pregnancy, no increased risk of jaundice or kernicterus was reported. It is important that your healthcare providers

know you are taking sulfasalazine so that if symptoms occur your baby can get the care that is best for them.

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

Studies have not been done to see if sulfasalazine can increase the chance of behavior or learning problems for the child.

Breastfeeding while taking sulfasalazine:

Sulfasalazine gets into breast milk in small amounts. Sulfasalazine is not expected to cause side effects in most infants. Children who have a weakened immune system (the body has a harder time fighting infections) or have a condition called glucose-6-phosphate dehydrogenase (G6PD) deficiency (a rare genetic condition in which red blood cells are fragile) might be more likely to experience side effects from sulfasalazine in breast milk. Diarrhea and bloody stools have been reported uncommonly in nursing infants when sulfasalazine was present in breast milk. If you suspect the child has any symptoms (such as diarrhea or bloody stools), contact the child's healthcare provider. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Some studies have reported oligospermia (less sperm than typical) and reduced sperm mobility (ability for sperm to move) in men taking sulfasalazine. This can affect a man's fertility (ability to get a woman pregnant). 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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