

## **Diclofenac**

This sheet is about exposure to diclofenac 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 diclofenac?

Diclofenac is a medication that has been used to treat pain and inflammation. It belongs to the class of medications called non-steroidal anti-inflammatory drugs (NSAIDs). Some brand names for diclofenac include Voltaren®, Volatarol®, Cataflam®, Solarze®. Diclofenac is sometimes sold in combination with acetaminophen as Parazone-DP®, and in combination with capsaicin as Capsinac® and Diclosaicin®.

Diclofenac can be given orally (by mouth), as an injection (shot), topically (applied to the skin), or as eye drops. Medication applied topically or as eye drops is usually found in lower levels in the blood than when taken orally or by injection. This means that using this medication topically or as eye drops would likely result in less exposure to a pregnancy than when used orally or by injection.

The U.S. Food and Drug Administration (FDA) recommends not using NSAIDs after week 20 of pregnancy, unless specifically recommended by your healthcare provider.

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

Some studies suggest that using diclofenac or other NSAIDs might make it harder to get pregnant. This might be more likely when NSAIDs are used often or over a long period of time.

Does taking diclofenac increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. It is not known if diclofenac can increase the chance of miscarriage. A few studies have reported an increased chance of miscarriage with diclofenac or other NSAID use. However, the reason why someone is taking the NSAID (such as a medical condition, infection, or pain from a miscarriage that is already happening) might contribute to the reported increased chance of miscarriage. As there can be many causes of miscarriage, it is hard to know if a medication, the medical condition being treated, or other factors are the cause of a miscarriage.

Does taking diclofenac 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 diclofenac, might increase the chance of birth defects in a pregnancy.

In a study of over 5,000 pregnancies, there was no increased chance of birth defects when NSAIDs (including diclofenac) were used during the first trimester of pregnancy. In another study of first trimester use of NSAIDs as a group (including diclofenac), there was an increased chance for heart defects. However, heart defects were not reported with diclofenac use specifically. Other factors in the study could have contributed to the reported increase in birth defects.

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

Diclofenac is not recommended for use after week 20 of pregnancy. Diclofenac should only be used under a healthcare provider's supervision, particularly in the 2nd and 3rd trimesters. Your healthcare providers can closely monitor your pregnancy if you need to use diclofenac after week 20.

There have been some reports that NSAID use in the 2nd half of pregnancy might affect the fetal kidneys and the amount of amniotic fluid (fluid that surrounds the fetus in the uterus). If there is not enough amniotic fluid (called oligohydramnios), other pregnancy complications, such as poor lung development and joint contractures (joints become stiff or unable to move), could happen. Oligohydramnios can also increase the chance that an early delivery is needed. In some cases, oligohydramnios could cause fetal demise (death).

One study suggested that the use of NSAIDS in the 1st half of pregnancy might also affect the fetal kidneys and

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amount of amniotic fluid. The researchers did not report which NSAIDs were included in their study.

Diclofenac use during the 3rd trimester (28 to 40 weeks of pregnancy) might also cause premature closure of the ductus arteriosus (an opening between the two major blood vessels leading from the heart). If the ductus arteriosus closes before it should, it can cause high blood pressure in the fetal lungs (pulmonary hypertension).

There are some studies on the class of NSAID medications that suggest NSAIDs can increase the chance of other pregnancy-related problems, including preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth. Other studies have not reported these findings. Some conditions that NSAIDs are used to treat can also increase the chance of these issues. That makes it hard to know if the medication, the condition being treated, or other factors are increasing the chance of these outcomes.

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

It is not known if diclofenac can increase the chance of behavior or learning issues for the child.

What screenings or tests are available to see if my pregnancy has birth defects or other issues?

Prenatal ultrasounds can be used screen for some pregnancy-related problems, such as oligohydramnios and fetal kidney function. Fetal echocardiograms can be used to identify premature closure of the ductus arteriosus. Ultrasound can also be used to monitor the growth of the pregnancy. Talk with your healthcare provider about any prenatal screenings or testing that are available to you. There are no tests available during pregnancy that can tell how much effect there could be on future behavior or learning.

Breastfeeding while taking diclofenac:

Diclofenac passes into breast milk in small amounts. Information is limited; however, most experts consider diclofenac to be acceptable during breastfeeding because diclofenac levels in milk are often so low that they are not able to be measured. Side effects have been reported in a breastfed child, but it was determined the side effects were caused by a different exposure. Diclofenac eye drops or topical application is not expected to get into breast milk in high amounts. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

It is not known if diclofenac could affect men's fertility (ability to get a woman pregnant). Studies have not been done to see if diclofenac could increase the chance of birth defects. In general, exposures that fathers or sperm donors 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.

Questions? Call 866.626.6847  $\mid$  Text 855.999.3525  $\mid$  Email or Chat at MotherToBaby.org.

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