

# Modafinil

## The safety of nuvigil during pregnancy or breastfeeding

The information provided below is for readers based in the United States of America. Readers outside of the United States of America should seek the information from local sources.

### **THIS MEDICATION MAY CAUSE HARM TO YOUR BABY:**

Nuvigil should only be taken during pregnancy if it is clearly needed. Results from a US-based pregnancy registry suggest that using this medication during pregnancy increases the risk of major fetal congenital malformations, including congenital cardiac anomalies. Additionally, animal studies indicate that taking Nuvigil during pregnancy may be harmful to the developing baby.

#### **What is Nuvigil?**

Nuvigil is a stimulant medication that is taken to prevent symptoms of excessive sleepiness. Nuvigil is currently available as a brand name and generic medication. The active ingredient in Nuvigil is armodafinil. Nuvigil is available in tablets and is taken once daily. It is only available by prescription from your doctor.

#### **What is Nuvigil used to treat?**

Nuvigil is used to improve wakefulness and decrease excessive drowsiness and sleepiness caused by obstructive sleep apnea (OSA), narcolepsy, or shift work disorder in adults. OSA is a condition in which the anatomy of the throat including the tongue fall against the airway, causing interruptions in breathing and sleep. Narcolepsy is a neurologic sleep condition that causes excessive daytime sleepiness.

#### **How does Nuvigil work?**

Nuvigil works by increasing the activity and amount of dopamine (a chemical) in your brain, to improve wakefulness. Nuvigil can also increase euphoria and alter mood and perception.

#### **If I am taking Nuvigil, can it harm my baby?**

In February 2019, Teva (one of the manufacturers of modafinil) informed Health Canada of the results of the 2018 annual report of the ongoing Nuvigil/Provigil (modafinil) Pregnancy Registry in the United States. The results suggest a higher rate of major congenital anomalies, and other adverse reactions, in children exposed to the drug in utero. This report documented cases of spontaneous abortion and of major congenital anomalies, including cardiac congenital anomalies. The frequency of major congenital anomalies (17.3%) and cardiac anomalies (4%) associated with the exposure to modafinil and/or armodafinil was above the frequency observed in the general population (3% and 1%, respectively). There have also been post-marketing reports of congenital malformations and of low fetal growth, as well as cases of babies who failed to thrive (poor physical development). Lastly, animal studies have shown that taking Nuvigil during pregnancy may cause harm to your baby.

Therefore, it is recommended to avoid Nuvigil during pregnancy, unless it is clearly indicated. There are also dangers associated with untreated sleep conditions during pregnancy.

### **Evidence from Animal Studies with Nuvigil:**

When given to pregnant rats and rabbits at similar doses used in humans, Nuvigil was associated with an increased risk of death of the baby, increased changes in bone formation, and decreased growth of the baby. Long-term effects after birth were not reported in animal studies.

Bottom line: Nuvigil should only be used during pregnancy if clearly indicated. There have been no human studies that have looked at the safety of Nuvigil during pregnancy. Animal studies have shown that Nuvigil may be harmful to the developing baby.

### **If I am taking Nuvigil and become pregnant, what should I do?**

If you are taking Nuvigil and become pregnant, you should contact your doctor immediately. Your doctor will determine if your medication is medically necessary, or if it should be discontinued until after the birth of your baby. Accidental exposure to Nuvigil during pregnancy is not expected to cause any major risk to your baby, but your doctor may recommend closely monitoring the baby's growth during your pregnancy.

### **If I am taking Nuvigil, can I safely breastfeed my baby?**

The manufacturer of this medication recommends weighing the benefits to the mother against the risks to the infant before deciding to continue or discontinue breastfeeding while taking Nuvigil. It is unknown if Nuvigil passes into human breast milk, affects breast milk production, or affects nursing infant development. If Nuvigil passes into breast milk, it could cause serious effects in the breastfed

baby. There is no data on the safety of Nuvigil in breastfed babies. If a nursing infant is exposed to Nuvigil, it is important to monitor the infant for signs of sleep disruption, anxiety, headache, and nausea. It is important to weigh the risks versus benefits of continuing this medication while breastfeeding.

**Bottom line: In breastfeeding moms who are taking Nuvigil, either breastfeeding or the medication should be discontinued. It is not known if Nuvigil passes into breast milk, and the effects of the medication on the breastfed baby are unknown.**

#### **If I am taking Nuvigil, will it be more difficult to get pregnant?**

There have been no studies in men or women that have looked at the effects of Nuvigil on fertility. In animal studies, use of Nuvigil increased the time to mating. The use of Nuvigil can decrease the effectiveness of oral birth control when used at the same time and for one month after discontinuation of Nuvigil. Women who are on Nuvigil and oral birth control are encouraged to use a backup form of birth control while taking Nuvigil and for at least one month following discontinuation of Nuvigil.

#### **If I am taking Nuvigil, what should I know?**

Nuvigil should not be used during pregnancy unless the medication is clearly indicated and the risks versus benefits of taking this medication have been considered. The report of the ongoing Nuvigil/Provigil (modafinil) Pregnancy Registry in the United States suggests a higher rate of major congenital anomalies, and other adverse reactions, in children exposed to the drug in utero.

In breastfeeding moms who are taking Nuvigil, either breastfeeding or the medication should be discontinued. It is not known if Nuvigil passes into human breast milk, and its effects on the breastfed baby are unknown.

#### **If I am taking any medication, what should I know?**

This report provides a summary of available information about the use of Nuvigil during pregnancy and breastfeeding. Content is from the product label unless otherwise indicated.

You may find Pregistry's expert report about sleep conditions [here](#). Additional information can also be found in the resources below.

For more information about **Nuvigil** and sleep conditions during and after pregnancy, contact <http://www.womenshealth.gov/> (800-994-9662 [TDD: 888-220-5446]) or check the following links:

Nuvigil.com: [Nuvigil Prescribing Information](#)

National Institute of Neurological Disorders and Stroke: [Narcolepsy Fact Sheet](#).

National Heart, Lung, and Blood Institute: [Sleep Apnea](#).

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## **General information**

It is very common for women to worry about having a miscarriage or giving birth to a child with a birth defect while they are pregnant. Many decisions that women make about their health during pregnancy are made with these concerns in mind.

For many women these concerns are very real. As many as 1 in 5 pregnancies end in a miscarriage, and 1 in 33 babies are born with a birth defect. These rates are considered the background population risk, which means they do not take into consideration anything about the health of the mom, the medications she is taking, or the family history of the mom or the baby's dad. A number of different things can increase these risks, including taking certain medications during pregnancy.

It is known that most medications, including over-the-counter medications, taken during pregnancy do get passed on to the baby. Fortunately, most medicines are not harmful to the baby and can be safely taken during pregnancy. But there are some that are known to be harmful to a baby's normal development and growth, especially when they are taken during certain times of the pregnancy. Because of this, it is important to talk with your doctor or midwife about any medications you are taking, ideally before you even try to get pregnant.

If a doctor other than the one caring for your pregnancy recommends that you start a new medicine while you are pregnant, it is important that you let them know you are pregnant.

If you do need to take a new medication while pregnant, it is important to discuss the possible risks the medicine may pose on your pregnancy with your doctor or midwife. They can help you understand the benefits and the risks of taking the medicine.

Ultimately, the decision to start, stop, or change medications during pregnancy is up to you to make, along with input from your doctor or midwife. If you do take medications during pregnancy, be sure to

keep track of all the medications you are taking.

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