

# Brintellix

## The safety of trintellix 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 CAN CAUSE HARM TO YOUR BABY:**

Trintellix should not be taken during pregnancy unless the benefits of treatment outweigh the potential risks to the baby. There have been no human studies that have looked at the safety of Trintellix during pregnancy, but animal studies indicate that taking Trintellix during pregnancy may be harmful to the developing baby. Taking antidepressants that affect serotonin, like Trintellix, during the third trimester of pregnancy may increase the risk of health problems in newborn babies.

#### **What is Trintellix?**

Trintellix is a medication that is taken to control the symptoms of depression in adults. Trintellix is currently only available as a brand name medication. The active ingredient in Trintellix is vortioxetine. This medication was originally marketed under the trade name, Brintellix. In 2016, the pharmaceutical companies that market Brintellix, Takeda Pharmaceuticals and Lundbeck, announced that the trade name would be changed to Trintellix. Both Brintellix and Trintellix contain the same active ingredient (vortioxetine), use the same dosing, and have the same expected outcomes. Nothing about the medication itself was changed. Trintellix is available in tablets and is taken once daily. It is only available by prescription from your doctor.

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

Trintellix is used to treat major depressive disorder in adults. Depression is a type of mood disorder that causes feelings of continuous sadness, despair, hopelessness, and/or loss of interest in daily activities for at least a 2-week period of time. These feelings can lead to symptoms of anxiety, irritability, fatigue, difficulty concentrating, changes in sleep patterns, feelings of worthlessness, or thoughts of suicide. If left untreated, these symptoms can interfere with your ability to function socially, at work or school, and in daily activities.

Moms can also experience postpartum depression. You can read about postpartum depression [here](#) and ways to prevent postpartum depression [here](#). You can also read about the differences between postpartum depression and baby blues [here](#).

### **How does Trintellix work?**

Trintellix works by increasing the activity and the amount of serotonin (a chemical) in your brain, to improve depression symptoms. It is thought that depression is caused by lower amounts of some chemicals, including serotonin.

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

The FDA warns that Trintellix should not be used during pregnancy unless the benefits of treatment outweigh the potential risks to the baby. Trintellix is a relatively new prescription medication that was released in 2013. There have been no human studies or case reports that have looked at the safety of this medication in pregnancy. Animal studies show that taking Trintellix during pregnancy may cause harm to your baby.

The FDA warns that taking antidepressants that affect serotonin, including Trintellix, late in pregnancy may cause your baby to be born with persistent pulmonary hypertension of the newborn (PPHN) and other health problems. These problems may require hospitalization, respiratory support (to help maintain normal breathing), and nutrition by injection of fluids (due to inability to feed). Other antidepressants that affect serotonin, such as selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs), are known to cause health problems in babies when taken by expecting moms. The health problems that have been reported in babies exposed to SSRIs or SNRIs are caused by their effects on serotonin. Since Trintellix affects serotonin similarly to SSRIs and SNRIs, it is possible that it may cause many of the same health problems. Your doctor will determine if Trintellix is medically necessary for your treatment, or if it should be discontinued until after the birth of your baby.

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

When given to pregnant rats and rabbits at much larger doses than the maximum recommended human dose, Trintellix was found to cause reduced birth weight, delayed bone development, and a higher rate of stillbirths (death of the offspring after 20 weeks of pregnancy). It was not associated with a higher rate of birth defects.

### **Evidence for the Risks of SSRIs or SNRIs in Human Babies:**

Babies whose moms have taken SNRIs or SSRIs late in the third trimester have developed health problems upon delivery. The following is a list of some health problems that have been reported in babies exposed to either SNRIs or SSRIs:

- Difficulty breathing
- Vomiting
- Difficulty feeding
- Constant crying
- Irritability
- Changes in body temperature
- Slowed and ineffective breathing
- Shakiness/jitteriness
- Low blood sugar levels
- Seizures
- Hyperactive reflexes
- A condition where breathing temporarily stops
- Poor blood flow or insufficient amounts of oxygen in the blood, leading to bluish colored skin
- “Floppy baby syndrome” (a condition characterized by too little muscle tone; babies often cannot control their neck muscles)
- A condition where muscles have too much muscle tone, causing spasms and stiff, rigid limbs

Using SSRIs in late pregnancy may also be associated with PPHN, a serious breathing problem in newborn babies that can lead to death. A study that looked at 836 healthy babies and 377 babies born with PPHN, found that taking SSRIs after the 20th week of pregnancy was associated with a 6 times higher risk of PPHN. Another study that looked at 831,324 babies born in Sweden found a 2.4 times higher risk of PPHN when moms reported taking SSRIs in early pregnancy and a 3.6 times higher risk when moms reported taking SSRIs in both early and late pregnancy.

Bottom line: Trintellix should not be used during pregnancy unless the benefits of treatment outweigh potential risks to the baby. There have been no human studies that have looked at the safety of Trintellix during pregnancy. Animal studies have shown that Trintellix may be harmful to the developing baby. Taking antidepressants that affect serotonin, like Trintellix, during the third trimester of pregnancy may increase the risk that your baby is born with various health problems.

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

If you are taking Trintellix 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.

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

The FDA warns that if breastfeeding moms are taking Trintellix, either breastfeeding or the medication should be discontinued. It is unknown if Trintellix passes into human breast milk. Animal studies have shown that Trintellix passes into the milk of rats. If Trintellix passes into breast milk, it could cause serious effects in the breastfed baby. There is no data on the safety of Trintellix in breastfed babies. The use of SSRIs and SNRIs (other antidepressants that affect serotonin) while breastfeeding has been associated with causing harmful side effects, such as sleepiness, poor feeding, and jitteriness in breastfed babies.

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

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

There have been no studies in men or women that have looked at the effects of Trintellix on fertility. Clinical trials have found that Trintellix may cause sexual disorders in both men and women.

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

Trintellix should not be used during pregnancy unless the benefits of treatment outweigh the potential risks to the baby. There have been no human studies that have looked at the effects of Trintellix in pregnancy. Taking antidepressants that affect serotonin, like Trintellix, during the third trimester of pregnancy may increase the risk of health problems in newborn babies.

In breastfeeding moms who are taking Trintellix, either breastfeeding or the medication should be discontinued. It is not known if Trintellix 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 Trintellix during pregnancy and breastfeeding. Content is from the product label unless otherwise indicated.

You may find Pregistry's expert report about depression [here](#), reports about other mental health disorders [here](#), and reports about the individual medications used to treat mental health disorders [here](#). Additional information can also be found in the resources below.

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

Takeda: [Brintellix \(vortioxetine\) Renamed Trintellix \(vortioxetine\) in U.S. to Avoid Name Confusion](#)

Mayo Clinic: [Depression \(major depressive disorder\)](#)

National Institute of Mental Health: [Depression](#)

WebMD: [Major Depression \(Clinical Depression\)](#)

**Last Updated: 24-03-2019**

## 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.