

A handy fact sheet on paliperidone and risperidone in pregnancy and breastfeeding

This fact sheet should be read alongside our other Choice and Medication leaflets, which include more information on this medicine and its side effects

What should I do if I am taking paliperidone or risperidone and want to start a family?

The best option is always to plan in advance. If you plan to start a family talk about this with your prescriber.

Paliperidone and risperidone are antipsychotics that can increase the levels of a hormone called prolactin in the body

If your prolactin is high, it may be more difficult to get pregnant. This can be checked by your prescriber by a simple blood test.

Possible options may include:

- **Continuing paliperidone or risperidone** if it is the best option for your health
- **Reducing the dose**, but only under guidance from your prescriber. Staying well is very important for both you and your baby
- **Switching to another medicine** that may carry fewer risks in pregnancy, although if paliperidone or risperidone are working for you, staying on this may be the safest option
- **Reviewing other medicines** you are taking and stopping those you no longer need.

Paliperidone is the main active metabolite of risperidone. This means that when your body processes risperidone, it turns part of it into paliperidone, which then contributes to its effects.

In terms of pregnancy and breastfeeding, the evidence and risks for paliperidone are considered similar to risperidone, because of their close relationship, though there are slightly fewer data for paliperidone itself

Paliperidone and risperidone are often used for serious mental health conditions such as **bipolar disorder** and **schizophrenia**. These illnesses can be high risk in pregnancy and after birth if not well managed. **Staying on the right medication can reduce those risks and help keep both you and your baby safe and well.**

I have just found out I am pregnant – should I stop taking paliperidone or risperidone?

- There is no urgent need to stop paliperidone or risperidone as your baby will have already been

exposed to the medicine

- Speak to your prescriber within the next day or two to discuss your options.
- Together, you can decide on a plan that works best for you. You may need some time to review the information and make an informed choice. The rest of this leaflet can help guide your decision.
- Without the paliperidone or risperidone you will be at risk of becoming unwell and making risky choices so if it has been helpful, it is usually best to carry on taking
- **If** stopping paliperidone or risperidone becomes part of your plan, agree with your care team on how you want to do this
- If you are taking paliperidone or risperidone regularly then stopping quickly may risk your symptoms coming back. Coming off it over several weeks or longer gives the body more time to adjust
- If you are taking these medicines as depot/long-acting injections, they are likely to stay in your system for a long part of the pregnancy, so stopping may not have any impact on baby but might increase your risk of getting unwell
- If you stop during pregnancy, you might want to go back on paliperidone or risperidone again after your baby has been born.
- **Untreated bipolar disorder or schizophrenia in pregnancy is high risk.** It can lead to relapse, hospital admission, self-harm, or difficulties caring for yourself and your baby.
- The perinatal period (pregnancy and the year after birth) is the highest risk time for relapse in bipolar disorder and schizophrenia
- Research shows:
 - Women with bipolar disorder or schizophrenia who stop medication during pregnancy have a higher chance of relapse.
 - Even if you continue medication, there is still a risk of relapse, but it is much lower than if you stop

- Staying on the right treatment greatly reduces the chance of relapse, which helps protect both you and your baby.

What are the risks of continuing paliperidone or risperidone during early pregnancy?

- The first trimester (months 1–3) is when your baby's organs are developing.
- Research on over 2,000 pregnancies where mothers took risperidone shows that the risk of miscarriage or major birth defects is not clearly increased, although data are limited
- Some studies suggest a very small increase in the overall risk of birth defects (for example, around 4% compared with a background risk of 3%), but specific problems have not been consistently reported
- There is no strong evidence that risperidone increases the chance of your baby being born small, early, or stillborn. Some data suggest that certain antipsychotics, including risperidone, may slightly increase the chance of having a larger baby or gestational diabetes, but the absolute risk is small
- Overall, current evidence is reassuring, but information is still limited. Your healthcare team can help you weigh these risks against the risks of untreated illness.

What about later on in pregnancy?

- During the second and third trimesters (from month 4 onwards), your body changes - your weight and fluid levels increase. This can reduce the amount of paliperidone or risperidone in your blood
- You will not usually need a higher dose, but everyone is different, so your symptoms should be monitored
- If you feel your medicine isn't working as well or your symptoms return, speak to your prescriber. A dose adjustment may be considered, but this is not always necessary
- Paliperidone and risperidone may slightly increase the chance of your baby being larger at birth, so your baby's growth may be monitored during pregnancy
- Some studies suggest that atypical antipsychotics, including paliperidone and risperidone, may slightly increase the risk of gestational diabetes. Your healthcare team may offer blood tests to check your blood

sugar, and your weight and blood pressure may be monitored during pregnancy

What about delivery time?

- If you need to take paliperidone or risperidone right up to delivery, your baby may have some temporary withdrawal symptoms after birth, sometimes referred to as withdrawal or discontinuation symptoms
- These can include being more sleepy than usual, being restless or agitated, having stiff or floppy muscles, shaking (tremors), or problems with breathing or feeding
- Not all babies will be affected, and if symptoms do occur, they are usually mild and go away within a few days
- Your baby will be checked closely after birth, especially if you are taking more than one medication that acts on the brain
- In most cases, these symptoms settle on their own, but hospital monitoring helps make sure your baby gets the right care if needed
- If your dose changed during pregnancy, you can usually go back to your pre-pregnancy dose once baby is born.

What about paliperidone or risperidone and breastfeeding?

- Due to paliperidone and risperidone increasing levels of the hormone prolactin you may find it easier to produce breast milk
- Paliperidone and risperidone pass into breast milk in very small amounts. Studies following infants whose mothers took paliperidone or risperidone during breastfeeding have not reported any problems
- If you are still taking your paliperidone or risperidone breastfeeding may help with any discontinuation symptoms
- If your baby is born early (pre-term) or has any health concerns, get advice from a healthcare professional first
- If you feel sleepy or sedated from paliperidone or risperidone, take care when handling your baby and avoid co-sleeping to reduce the risk of accidental harm.
- If your baby becomes restless, very sleepy or develops feeding problems stop breastfeeding (if you can) and quickly seek medical advice.
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What about later on in baby's development?

- A single study of up to 1,404 children with gestational exposure to risperidone found no increased risk of neurodevelopmental disorders, including autism spectrum disorder (ASD), attention deficit hyperactivity disorder (ADHD), learning difficulties, speech/language disorders, developmental coordination disorder, intellectual disability, or behavioural problems.
- Overall, current evidence suggests that exposure to paliperidone or risperidone during pregnancy and breastfeeding is unlikely to have a lasting impact on your child's behaviour, learning, or physical development.

What else can I do to help myself stay well?

- Depending on why you are taking paliperidone or risperidone, consider **talking therapies**, which can be helpful on their own or alongside medication.
- Avoid taking any unnecessary medications. **Check with a pharmacist** before using over-the-counter medicines.

- Eat a **healthy, balanced diet** with plenty of fruits and vegetables.
- Stay **active** with regular exercise, as recommended by your healthcare provider.
- **Drink enough water** to stay hydrated, especially if you feel thirsty.
- If you experience **morning sickness**, you may be at higher risk of dehydration. Drink plenty of fluids and speak to your doctor—there are treatments that can help.
- Ask your healthcare team if you need any **vitamin supplements**, such as folic acid, iron, or vitamin D.
- Attend any **recommended blood tests** or health check-ups.
- If you're feeling **stressed**, explore non-medication ways to relax, but try to distinguish between normal pregnancy changes and signs of becoming unwell.

Remember:
Babies do better with well mums

The small print: This leaflet is to help you understand more about risperidone/paliperidone in pregnancy. You **must** also read the manufacturer's Patient Information Leaflet (PIL). Go to our website for fuller answers to many other questions.

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