

Patient summary

Sertraline is a medication prescribed for the treatment of depression or anxiety disorders. Sertraline users often start with a low dose that is gradually increased until an effective dosage is reached to manage symptoms. The corresponding dose is then maintained. The dose (amount) of sertraline received by pregnant women to treat their depressive and/or anxiety symptoms may sometimes be higher than outside of pregnancy.

What are the benefits and risks of using sertraline during pregnancy?

Sertraline can be used during pregnancy. An important benefit is that it reduces a mother's depression and anxiety symptoms. This is also likely to benefit the child because a mother's poor condition may increase the risk of preterm birth and low birth weight of the baby. Other studies have found that sertraline use may increase the risk of preterm birth and low birth weight of the baby, however it is unclear if these effects are due to sertraline, the underlying illness of the mother or other factors. Sertraline may slightly increase the risk of treatable heart defects in the child but this risk is small. However more recent studies have not found this link. Sertraline use, especially in the third trimester, increases the risk of high blood pressure in the newborn's lungs, a severe illness. However, the likelihood of this risk occurring remains very low even when sertraline is used. Sometimes, sertraline may cause short-term withdrawal symptoms in a newborn baby, for example slight shaking and crying. These symptoms usually disappear on their own within a few days after birth. It is recommended that babies whose mothers used sertraline during the third trimester of pregnancy be born in the hospital so they can be monitored for withdrawal symptoms and respiratory issues.

Should pregnant women use a different dose than non-pregnant individuals?

To date, there has been little research on the most suitable sertraline dose for pregnant women. Because a woman's body changes during pregnancy, she might require a different dose compared to adults who are not pregnant. We reviewed the literature to determine an optimal dosing strategy for sertraline during pregnancy. This included looking at studies using computer models that mimic changes in a pregnant woman's body and assess the suitability of different doses at various stages of pregnancy.

- The effects of sertraline for a given dose can vary between individuals. This likely stems from differences in how sertraline is processed and removed from the body, possibly due to genetic differences between people. That's why patients may use different doses of sertraline.
- There isn't a defined amount, such as a given dose or blood concentration, where sertraline becomes harmful to the user. Harmful effects are very rare outside of pregnancy, which is likely the case for pregnant women as well.
- During pregnancy, changes in a woman's body are likely to lower sertraline levels in the blood, especially in the second and third trimesters, compared to before pregnancy. Hence, the sertraline dose should generally not be decreased during pregnancy and may even need to be higher for certain pregnant women in the second or third trimester. This depends on how a pregnant woman responds to treatment over time: the dose may have to be increased because the effect on her symptoms is less than before pregnancy or insufficient if she just started treatment. Therefore, it is important to monitor a woman's symptoms of depression during pregnancy, so that the dose can be adjusted accordingly.
- Even when the dose is increased during pregnancy, it should always remain within the dosing range for non-pregnant individuals.

Could a higher dose be harmful to the baby?

There is little information on whether a higher sertraline dose leads to harm for the baby. Higher doses may increase the chance of side effects such as reduced birth weight and high blood pressure in the newborn's lungs. However, even when using sertraline, the likelihood of these conditions occurring is very low. Evidence has been found on a link between higher sertraline doses and withdrawal symptoms in the newborn baby. This link was only seen when sertraline is used in the third trimester. The risk of heart defects is unlikely to be linked to the dose because such defects only occur when the babies' organs are being formed in the first trimester when the dose is unlikely to be increased. Overall, the risks of increasing the dose of sertraline during pregnancy for the baby are deemed low because increased doses will remain within the normal dosing range of sertraline for which fetal safety data have been obtained.

Could a higher dose be harmful to the pregnant woman?

The risk for a pregnant woman to receive too much sertraline is low. There are almost never signs of harm from higher sertraline doses outside of pregnancy. This is likely to also be the case during pregnancy given that sertraline levels for a given dose tend to be lower. In addition, an 'overdose' appears unlikely because the dose is gradually increased based on the pregnant woman's symptoms.

Risks and benefits for the proposed sertraline dosing strategy during pregnancy compared to the standard dose

Proposed dosing strategy: increase the dose within the normal range if symptoms worsen during pregnancy; adjust the dose progressively based on the pregnant woman's symptoms.

Risks for the mother	Benefits for the mother
- None expected: no harmful effects within normal dose range in users who are not pregnant ↔	- Better control of depression or anxiety symptoms linked to reduced likelihood of harmful behaviors and other pregnancy complications such as preterm birth ↑ - Risk of postpartum depression* ↓
Risks for the baby	Benefits for the baby
- Possible risk of reduced birth weight ↑ - Low risk of high blood pressure in the lungs when using sertraline in the third trimester ↑ - Risk of short-term withdrawal symptoms at birth when sertraline is used in the third trimester ↑	- Indirect benefits due to better controlled depression in the mother ↑ - Potential improved bonding due to reduced risk of postpartum depression in the mother ↑

*Postpartum depression is a type of depression that some people experience after having a baby

↑ = likelihood demonstrably increases with dose adjustment (evidence on dose-effect relationship)
 ↑↑ = likelihood theoretically increases with dose adjustment (no evidence on dose-effect relationship)
 ↓ = likelihood demonstrably decreases with dose adjustment (evidence on dose-effect relationship)
 ↓↓ = likelihood theoretically decreases with dose adjustment (no evidence on dose-effect relationship)
 ↔ = likelihood unchanged with dose adjustment

Bold: risks that carry relatively more weight
Green arrow: beneficial effects of dose adjustment
Blue arrow: neutral effects of dose adjustment
Red arrow: detrimental effects

Final decision:

The proposed dosing strategy appears reasonable based on the following: because the possible risks of increased sertraline doses for the baby occur rarely or resolve within days, these risks are considered to weigh less than the benefits of effectively treating a pregnant woman's depression and anxiety during pregnancy, benefitting her and her child.