Azelastine

This sheet is about exposure to azelastine in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is azelastine?

Azelastine is an antihistamine. It is commonly used to treat allergy symptoms. It comes as a nasal spray (intranasal) to treat symptoms such as runny, itchy, and stuffy nose and sneezing. Azelastine is sold under the brand name Astelin®. Azelastine also comes in eye drop form to treat itchy eyes due to allergies. It is sold under the brand name Optivar®.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

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

Studies have not been done in humans to see if azelastine could make it harder to get pregnant.

Animal studies have shown no impact on female fertility in rats when azelastine was used by mouth (orally) at levels up to 150 times the maximum recommended human daily intranasal (by nose) dose in adults.

Does taking azelastine increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. Studies have not been done to see if azelastine increases the chance of miscarriage.

Does taking azelastine increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Studies have not been done in humans to see if azelastine could increase the chance of having a pregnancy with a birth defect.

Animal studies that used doses of azelastine that would be used in humans have not shown an increased chance for birth defects.

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

Studies have not been done to see if azelastine increases the chance for pregnancy related problems such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces (2500 grams) at birth).

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

Studies have not been done to see if azelastine can cause behavior or learning issues for the child.

Breastfeeding while taking azelastine:

When used in eye drop form, the amount of the azelastine absorbed is small, and is not expected to cause any problems in breastfed infants. When used as directed for a few days, azelastine nasal spray would also not be expected to cause any adverse effects in breastfed infants. Because azelastine tastes bitter, the baby may reject breastfeeding. If the nasal spray is used in larger doses or for more than a few days, it may cause drowsiness and other effects in the infant. It may also lower milk supply, especially when used with a medication called pseudoephedrine or before breastfeeding is well established. Antihistamines that do not cause drowsiness (non-sedating) are preferred alternatives. If you suspect the baby has any symptoms (such as drowsiness), contact the child’s healthcare provider. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

If a male takes azelastine, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?
Studies have not been done to see if azelastine could affect human male fertility or increase the chance of birth defects. Animal studies have shown no change on male fertility in rats when azelastine was used by mouth (orally) at levels up to 150 times the maximum recommended human daily intranasal dose in adults. In general, exposures that fathers or sperm donors have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

**Selected References:**