Azelastine

This sheet talks 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®.

I take azelastine. Can it make it harder for me to get pregnant?
Studies on women have not been done to see if azelastine could make it harder for a woman 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 dose in adults.

I just found out I am pregnant. Should I stop taking azelastine?
Talk with your healthcare providers before making any changes to this medication.

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 in the first trimester increase the chance of birth defects?
In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. Studies have not been done 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 risk for birth defects.

Could taking azelastine in the second or third trimester cause other pregnancy complications?
Studies have not been done to see if azelastine causes pregnancy complications.

Does taking azelastine in pregnancy cause long-term problems in behavior or learning for the baby?
Studies have not been done to see if azelastine causes long-term problems in behavior or learning problems.

Can I breastfeed while taking azelastine?
Yes. 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. 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 pseudoephedrine or before breastfeeding is well established. Because azelastine tastes bitter, the baby may reject breastfeeding. Antihistamines that do not cause drowsiness (non-sedating) are preferred alternatives. Be sure to talk to your health care provider about all of your breastfeeding questions.
If a man takes azelastine, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?

There are no studies looking at possible risks to a pregnancy when the father takes azelastine. Animal studies have shown no impact 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 have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

Selected References:

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