Tildrakizumab (Ilumya®)

This sheet is about exposure to tildrakizumab in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What is tildrakizumab?

Tildrakizumab (Ilumya®) is a medication that has been used to treat moderate-to-severe plaque psoriasis. For more information about psoriasis in pregnancy, please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/.

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 your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

I am taking tildrakizumab, but I would like to stop taking it before getting pregnant. How long does the drug stay in my body?

The time it takes the body to metabolize (process) medication is not the same for everyone. In healthy non-pregnant adults, it takes up to 138 days (about 5 months), on average, for most of the tildrakizumab to be gone from the body.

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

Studies have not been done in humans to see if tildrakizumab could make it harder to get pregnant. Animal studies did not report an effect on fertility (ability to get pregnant).

Does taking tildrakizumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. A report of 14 human pregnancies exposed to tildrakizumab in the first trimester noted miscarriages in 2 of those 14 pregnancies. This is similar to the rate of miscarriage in the general population. Animal studies did not report a higher chance of miscarriage.

Does taking tildrakizumab increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like tildrakizumab, might increase the chance of birth defects in a pregnancy. In a report on 14 human pregnancies exposed to tildrakizumab in the first trimester, no birth defects were reported in the infants. Animal studies done by the manufacturer also did not show a higher chance of birth defects with exposure to tildrakizumab.

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

Studies have not been done in humans to see if tildrakizumab increases the chance of 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 tildrakizumab in pregnancy affect future behavior or learning for the child?

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

Can my baby receive live vaccines before one year of age if I take tildrakizumab later in pregnancy?

Since tildrakizumab may suppress the immune system of the person taking it, there is a theoretical concern that the same thing could happen to the baby if they are exposed during pregnancy. If someone has a weakened immune system, they may be more likely to develop an infection from a live vaccine. Live vaccines contain a small amount of live virus. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. In the

United States, rotavirus is the only live vaccine routinely given in the first year of life. Most people can get inactivated vaccines in the first year of life.

Talk with your child's healthcare provider about your exposure to tildrakizumab during pregnancy. They can talk with you about the vaccines your child should receive and the best time for your child to receive them.

Breastfeeding while taking tildrakizumab:

Tildrakizumab has not been studied for use during breastfeeding. Tildrakizumab is a very large protein, so not much of the medication is likely to pass into breast milk. Any small amounts that might get into the breast milk are likely to be destroyed in the baby's stomach. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes tildrakizumab, could it affect his fertility or increase the chance of birth defects?

Studies have not been done in humans to see if tildrakizumab could affect male fertility (ability to get a woman pregnant) or increase the chance of birth defects. Animal studies did not report an effect on male fertility. In general, exposures that fathers or sperm donors 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/.

> *MotherToBaby is currently conducting a study looking at tildrakizumab and other medications in pregnancy. If you are interested in learning more, please call 1-877-311-8972 or visit https://mothertobaby.org/join-study.*

Please click here for references.

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