Rebif

The safety of interferon-beta during pregnancy or breastfeeding

The information provided below is for readers based in the United States of America. Readers outside of the United States of America should seek the information from local sources.

THIS MEDICATION MAY CAUSE HARM TO YOUR BABY:

Although there is limited available information on the safety of interferon-beta in human pregnancy, it is generally recommended that it be stopped during pregnancy except in select women with a high risk of relapsing multiple sclerosis. Information is limited related to the safety of interferon-beta in nursing infants, and it is recommended to weigh the risks versus benefits of this medication before taking it while breastfeeding.

What is interferon-beta?

Interferon-beta is an immunomodulator or disease-modifying medication available as interferon-beta 1a (Avonex™, Rebif™) and interferon-beta 1b (Betaseron™, Extavia™). Avonex™ is administered as an intramuscular injection weekly, and Rebif™ is administered as a subcutaneous injection three times weekly. Betaseron™ is administered as a subcutaneous injection every other day. Interferon-beta 1a and interferon-beta 1b are only available as brand name medications (no generics are currently available) by prescription from your doctor.

What is interferon-beta used to treat?

Interferon-beta is used to treat relapsing forms of multiple sclerosis. Multiple sclerosis is a chronic disease that affects the brain and spinal cord. The severity of symptoms can vary, and can include difficulty walking and talking. Pregnancy has not been shown to negatively affect the course of multiple sclerosis, however, symptoms of multiple sclerosis can make pregnancy difficult (e.g., fatigue, weakness) as well as increase the difficulty of labor and delivery. Frequent check-ups and symptom management using medications such as anti-inflammatories may be recommended during pregnancy.

You can find out more about multiple sclerosis in pregnancy here.

How does interferon-beta work?

Interferon-beta works by increasing the activity of immune cells and modifying immune activities including suppression of inflammatory processes. Interferon-beta decreases the relapse rate and disease severity in multiple sclerosis patients.

If I am taking interferon-beta, can it harm my baby?

There is limited information available on the safety of interferon-beta in human pregnancy. However, animal studies suggest there is moderate risk of harm to the developing baby associated with this medication. Interferon-beta should only be used during pregnancy after considering the risks to the baby and benefits to the mother.

Disease-modifying agents for treatment of multiple sclerosis are typically stopped before planned pregnancy except in women who are at a high risk of relapsing multiple sclerosis activity. Interferon-beta 1a and interferon-beta 1b can be used until pregnancy is confirmed, and then can be continued throughout pregnancy to select women with active multiple sclerosis. Pregnancy is generally recommended to be delayed in women with high multiple sclerosis disease activity.

Evidence from animal studies with interferon-beta:

When given to pregnant monkeys at doses up to 40 times the maximum recommended human dose on gestation days 20-70, there was no increase in birth defects. However, doses 2.8-40 times the maximum recommended human dose was associated with increased abortive activity. In pregnant rats exposed to 310 times the maximum recommended human dose of interferon-beta, there was no reported increase in birth defects in offspring. Newborn mice and rats injected with interferon-beta developed growth delays, liver cell death, cysts in the lungs, inflammation of the kidneys, or died.

Evidence for the risks of interferon-beta in human babies:

It is unknown if interferon-beta crosses the placenta to reach the baby. Although clinical trials of interferon-beta exposure in pregnancy report a majority of pregnancies are carried full-term and result in healthy babies, pregnant women are still encouraged to discontinue interferon-beta 1a before becoming pregnant due to the limited availability of safety information.

Several studies in women exposed to interferon-beta in early pregnancy have reported no increase in or pattern of birth defects. The Betaseron Multiple Sclerosis clinical trial reported four miscarriages in

participants. Most studies have found no association between interferon-beta exposure in pregnancy and miscarriages. However, studies of interferon-beta exposure during pregnancy report an association with low birth weight, preterm birth, and birth length, but no difference in birth defects, cesarean delivery, or miscarriages. The German Multiple Sclerosis and Pregnancy Registry compared 251 pregnancies with interferon-beta exposure to 194 pregnancies without exposure, finding no difference in birth weight, preterm birth, miscarriages, or birth defects. A comparison of Finnish and Swedish pregnancies exposed to interferon-beta and not exposed to interferon-beta found no difference in birth weight, length, or head circumference. A study of 425 pregnancies recorded in a global drug safety database reported a similar risk of birth defects and miscarriages for pregnancies exposed to interferon-beta and pregnancies in the general population unexposed to interferon-beta 1a. A large cohort study of pregnancies exposed to interferon-beta 1b found similar rates of miscarriages and birth defects as the general population. A study of women contacting the Motherisk Program regarding exposure to interferon-beta 1a or interferon-beta 1b related to the diagnosis of multiple sclerosis during pregnancy reported an increased risk of loss of the baby and low birth weight associated with exposure to this medication during pregnancy. Babies exposed to interferon-beta in utero may have a lower birth weight, but developmental milestones were normal. Pregnant women discontinuing interferon-beta 4 weeks before conception had a lower risk of miscarriages, birth defects, or complications in the baby. However, exposed babies did have a lower birth weight and length. One case report discussed a pregnant woman who received interferon-beta 1a throughout her pregnancy without any reported adverse pregnancy complications. The Betaseron Pregnancy Registry evaluated pregnant women exposed to interferon-beta 1b in the first and third trimester of pregnancy, finding no increase in risk of birth defects and no adverse developmental outcomes in 4 month old infants.

Bottom line: There is limited safety information available on the use of interferon-beta during human pregnancy. Interferon-beta should only be used during pregnancy after considering the fetal risks and maternal benefits.

If I am taking interferon-beta and become pregnant, what should I do?

If you are taking interferon-beta and become pregnant, you should contact your doctor immediately. Your doctor will determine if your medication is medically necessary, or if it should be discontinued until after the birth of your baby.

If I am taking interferon-beta, can I safely breastfeed my baby?

Interferon-beta is expected to be minimally excreted into breast milk, with the nursing infant estimated to receive a tiny amount (0.006%) of the mother's dose of the medication. There are no human studies evaluating the safety of interferon-beta in nursing infants, its impact on milk production, or its presence in human milk. The Multiple Sclerosis Centre of Excellence on Reproduction and Child Health and French guidelines consider interferon-beta moderately safe while breastfeeding. There have been no reports of adverse events in nursing infants exposed to interferon-beta through breast milk. There were no reported developmental delays in most infants exposed to interferon-beta through nursing in the German Multiple Sclerosis and Pregnancy Registry. It is recommended to weigh the potential benefits and risks before using this medication while breastfeeding.

Bottom line: Evidence on the safety of interferon-beta while breastfeeding is limited. It is recommended to weigh the potential benefits and risks before using this medication while breastfeeding

If I am taking inter
feron-beta, will it be more difficult to get pregnant?

There is limited information available on the effects of interferon-beta on fertility and reproductive potential in humans. Studies in monkeys exposed to interferon-beta suggest there are no adverse effects of this medication on menstrual cycle duration or hormones.

If I am taking interferon-beta, what should I know?

There is limited information available regarding the safety of interferon-beta during pregnancy and while breastfeeding. Although many studies have suggested there is no increased risk of adverse effects on the baby with exposure to this medication, animal studies suggest the possibility of risk. It is generally recommended to stop using interferon-beta during pregnancy, except in select women with a high risk of relapsing multiple sclerosis during pregnancy. There have been no adverse events reported in nursing infants exposed to interferon-beta in breast milk; however, it is recommended to weigh the risks and benefits before continuing this medication while breastfeeding.

If I am taking any medication, what should I know?

This report provides a summary of available information about the use of interferon-beta during pregnancy and breastfeeding. Content is from the product label unless otherwise indicated.

You may find Pregistry's expert reports about neurological disorders and the individual medications used to treat them here, and a report about multiple sclerosis here. Additional information can also be

found in the resources below.

For more information about **interferon-beta** during and after pregnancy, contact http://www.womenshealth.gov/ (800-994-9662 [TDD: 888-220-5446]) or check the following link:

Bayer Healthcare: Betaseron Prescribing Information

Johns Hopkins Medicine: Multiple sclerosis and pregnancy

U.S. National Library of Medicine: LACTMED: INTERFERON-BETA

Last Updated: 15-07-2020

General information

It is very common for women to worry about having a miscarriage or giving birth to a child with a birth defect while they are pregnant. Many decisions that women make about their health during pregnancy are made with these concerns in mind.

For many women these concerns are very real. As many as 1 in 5 pregnancies end in a miscarriage, and 1 in 33 babies are born with a birth defect. These rates are considered the background population risk, which means they do not take into consideration anything about the health of the mom, the medications she is taking, or the family history of the mom or the baby's dad. A number of different things can increase these risks, including taking certain medications during pregnancy.

It is known that most medications, including over-the-counter medications, taken during pregnancy do get passed on to the baby. Fortunately, most medicines are not harmful to the baby and can be safely taken during pregnancy. But there are some that are known to be harmful to a baby's normal development and growth, especially when they are taken during certain times of the pregnancy. Because of this, it is important to talk with your doctor or midwife about any medications you are taking, ideally before you even try to get pregnant.

If a doctor other than the one caring for your pregnancy recommends that you start a new medicine while you are pregnant, it is important that you let them know you are pregnant.

If you do need to take a new medication while pregnant, it is important to discuss the possible risks the medicine may pose on your pregnancy with your doctor or midwife. They can help you understand the benefits and the risks of taking the medicine.

Ultimately, the decision to start, stop, or change medications during pregnancy is up to you to make, along with input from your doctor or midwife. If you do take medications during pregnancy, be sure to keep track of all the medications you are taking.