New Reyataz Dosing Recommendations for HIV-Positive Pregnant Women

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Bristol-Myers Squibb (BMS) has issued new dosing recommendations for HIV-positive pregnant women who wish to use Reyataz (atazanavir) as part of an antiretroviral (ARV) regimen. The new dosing recommendation is particularly important for treatment-experienced women using tenofovir (found in Viread and Truvada) or an acid-reducing H2 receptor antagonist.

Determining the proper dose of antiretroviral (ARV) drugs during and immediately following pregnancy is not always simple. During the last three months of pregnancy—referred to as the third trimester—the volume of blood in the woman's body increases significantly, as do certain hormones that can affect how quickly drugs get broken down. This means that the concentrations of certain drugs in the blood during this time period can become too low to remain effective.

The risk of lowered efficacy, combined with the challenges and risks of studying drugs in pregnant women, means that dosing recommendations for pregnant women are often delayed years after a drug is approved for adults in the general population.

Now BMS has announced the results of a study that charted how blood levels of Reyataz change during and immediately following pregnancy. In general, blood levels of Reyataz went down during the third trimester of pregnancy and were increased in the couple of months immediately following the birth of the baby—known as postpartum.

Based on analyses of these data, BMS—in conjunction with the U.S. Food and Drug Administration—is recommending different Reyataz dosing schedules during the third trimester, which depend on a pregnant woman's treatment history along with the other medications she is using. The company also recommends that all pregnant women be watched carefully for increases in side effects during the postpartum period.

BMS reiterates that Reyataz should always be used in combination with Norvir during pregnancy. Though unboosted Reyataz—Reyataz not used in conjunction with low-dose Norvir—is an approved treatment option, it is not recommended for pregnant women.

Generally speaking, pregnant women can use the standard Norvir-boosted Reyataz dose: 300

milligrams (mg) Reyataz combined with 100 mg Norvir.

Women in the second or third trimester of pregnancy who are treatment experienced—meaning they have been on other HIV drug regimens in the past—and are taking the drug tenofovir or an H2 receptor antagonist should take 400 mg Reyataz combined with 100 mg Norvir. Examples of H2 receptor antagonists include Tagamet (cimetidine), Pepcid (famotidine) and Zantac (ranitidine).

According to BMS, there aren’t enough data to recommend a proper dose of Reyataz for treatment-experienced pregnant women using both tenofovir and an H2 receptor antagonist at the same time.

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