FDA Updates Atripla Label

April 22, 2013

The U.S. Food and Drug Administration (FDA) has made changes to the label for the single-pill HIV antiretroviral combination therapy Atripla (efavirenz/emtricitabine/tenofovir). Among those changes and additions are:

- An advisory against taking Atripla with Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir).
- Information on drug interaction for raltegravir, boceprevir and telaprevir.
- Additional information about a rash warning, advising those with a life-threatening reaction such as Stevens-Johnson syndrome to consider alternative HIV therapy.
- A statement that the appropriate dosing for a combination of efavirenz and boosted Invirase (saquinavir/ritonavir) has not been established.
- Information about dosing with boosted Kaletra (lopinavir/ritonavir), with an advisory that those taking the pair in combination with Atripla should be monitored for adverse reactions.
- In an addition to the advisory that HIV-positive mothers should not breast-feed their infants because of the risk of transmitting the virus, the FDA states that studies in rats have shown that efavirenz is secreted in milk and that human studies have shown that both tenofovir and emtricitabine are excreted in breast milk. Because the risks of infant exposure to these agents are unknown, mothers should not breast-feed while taking Atripla.

To read the FDA release, click here.