FDA Updates the Labels of Intelence (Etravirine) and Prezista (Darunavir)

March 5, 2013

The U.S. Food and Drug Administration has approved changes to the labels for the antiretrovirals (ARVs) Intelence (etravirine) and Prezista (darunavir).

The changes to the Intelence label are as follows:

- There have been reports of severe, potentially life-threatening and fatal skin reactions. Among these are Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme.
- Hypersensitivity reactions include Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), characterized by rash and sometimes organ dysfunction, including liver failure.
- Grade three and four rash occurred in about 1 percent of those taking Prezista in a Phase III trial. Women were more likely than men to experience rash, which occurred most commonly during the first 6 weeks of therapy. A total of 2.2 percent of those in the Phase III trial discontinued therapy due to rash.
- Drug interactions include:
    - Antimalarials: artemether/lumefantrine. Caution is advised when taking Intelence with artemether/lumefantrine because it is not known whether Intelence may reduce antimalarial efficacy.
    - Hepatitis C virus (HCV) direct-acting antivirals: telaprevir. The combination leads to no change in Intelence levels, but it does lead to a decrease in telaprevir. There are insufficient data to make a dosing advisement for telaprevir in combination with Intelence.

The changes to the Prezista label include:

- Antimalarials: artemether/lumefantrine. Prezista can be used without dose adjustments, but the combination should be used with caution because an increase of lumefantrine exposure may raise the risk of QT prolongation (irregular heart rhythm).

To read the FDA release on Intelence, click here.

To read the FDA release on Prezista, click here.

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