Nevirapine (Viramune) Sensitivity

Pharmacologic agent: Nevirapine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) with activity against Human Immunodeficiency Virus Type 1 (HIV-1).

WARNING: LIFE-THREATENING (INCLUDING FATAL) HEPATOTOXICITY and SKIN REACTIONS

Hepatoxicity: Severe, life-threatening, and in some cases fatal hepatotoxicity, particularly in the first 18 weeks, has been reported in patients. Female gender and higher CD4⁺ cell counts at initiation of therapy place patients at increased risk; women with CD4⁺ cell counts > 250 cells/mm³, including pregnant women receiving nevirapine in combination with other antiretrovirals for the treatment of HIV-1 infection, are at the greatest risk.

Skin Reactions: Severe, life-threatening skin reactions, including fatal cases, have occurred in patients treated with nevirapine. These have included cases of Stevens-Johnson syndrome, toxic epidermal necrolysis, and hypersensitivity reactions characterized by rash, constitutional findings, and organ dysfunction.

Pharmacogenomic information: Patients who carry the HLA-B*3505 allele and are of Thai descent appear to be at high risk for developing a hypersensitivity skin reaction to nevirapine¹. This finding needs to be confirmed in additional studies and other populations. The FDA has not changed the label at this time.

Action:

 Screening for the HLA-B*3505 allele could be considered in patients of Thai descent who are being started on Nevirapine. If this is present consideration of an alternative may be appropriate.

Reference & Resources

1. Soranun, C. et al. (2009) <u>HLA-B*3505 allele is a strong predictor for nevirapine-induced skin adverse drug reactions in HIV-infected Thai patients</u>. Pharmacogenet Genomics. 19:139-46. (http://www.ncbi.nlm.nih.gov/pubmed/19104471)

General drug information obtained from RxList: http://www.rxlist.com/viramune-drug.htm