Second-Generation Non-Nuke Approved for Children 6 and Older

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Children between 6 and 17 years old may now use Intelence (etravirine), a non-nucleoside reverse transcriptase inhibitor (NNRTI) that has shown to be effective for treatment-experienced people living with HIV, notably those with virus resistant to first-generation NNRTI options efavirenz (found in Sustiva and Atripla) or nevirapine (Viramune).

According to a U.S. Food and Drug Administration announcement of the pediatric approval, a new scored 25 milligram (mg) tablet was also green-lighted by the agency and will be manufactured by Intelence's manufacturer, Janssen Therapeutics.

Until now, Intelence has been approved only for treatment-experienced HIV-positive adults. The drug is widely considered to be an important addition to the list of approved HIV treatments given its established efficacy against HIV strains resistant to efavirenz and, to a lesser extent, nevirapine.

Viramune is frequently prescribed for young children, as it is available in a liquid solution. Sustiva is only available in pill form, though a lower-dose 50 mg formulation is available for older children who are able to swallow tablets.

According to the FDA-approved revisions to the Intelence package insert, the recommended dose for children at least 6 years old and weighing no less than 35.2 pounds (16 kilograms) is based on body weight, though the dose should not exceed the recommended daily amount for adults (200 mg twice daily).

The 25 mg Intelence tablets should be taken orally, following a meal. If taking the tablets whole isn't possible, the pills can be dissolved in a glass of water or a mix of water with milk or orange juice.

The approval of Intelence for children is based on the successful completion of Study C213, in which 101 HIV treatment-experienced children between 6 and 17 years old received Intelence in combination with other antiretrovirals.

The frequency, type and severity of side effects were comparable to those observed in adult subjects, except for rash, which was observed more frequently in children. The most common side

effects, occurring in at least 2 percent of those enrolled in the study, were rash and diarrhea. In the majority of cases, rash was mild to moderate, occurred in the second week of therapy and generally cleared up within one week on continued therapy.

After 24 weeks of treatment, 52 percent of all children in the trial had undetectable viral loads. CD4 counts increased, on average, by 112 cells after six months.

The safety and efficacy of Intelence have not been established in children younger than 6 years old.

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