Viramune Prescribing Information Updated

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Children should be prescribed Viramune (nevirapine) based on the total surface area of their bodies rather than by weight, says a U.S. Food and Drug Administration (FDA) announcement regarding revisions to Viramune's prescribing information. Recommendations regarding rashes and lead-in dosing and use of Viramune in people with liver impairment are also discussed.

Previous prescribing information for infants and children allowed health care providers to choose whether to provide Viramune based solely on a child's weight or based on total body surface area (BSA), which is calculated using a formula that includes a child's height and weight. Recent data, however, reveal that dosing based on BSA is more likely to result in desired blood levels of Viramune than is dosing based on weight. For this reason, it is now recommended that providers prescribe Viramune based only on BSA. Specifically, children 15 days and older should be given 150 milligrams of Viramune per meter squared of BSA once daily for the first 14 days, followed by 150 milligrams per meter squared of BSA twice daily thereafter.

The management of rash in adults and children is also reviewed in the new prescribing information. Current guidelines recommend starting Viramune at half the ultimate daily dose for the first 14 days and then switching to the full dose on day 15. The new prescribing information recommends that a person not increase their dose on day 15 if experiencing a rash. However, the lower lead-in dose should not be taken longer than 28 days. If a rash persists, Viramune should be switched for a comparable antiretroviral.

Lastly, the new prescribing information addresses the treatment of people with liver impairment. The new prescribing information recommends that people with moderate liver impairment avoid using Viramune. Previously, only those with severe liver impairment were cautioned to avoid using the drug. This is because people with either moderate or severe liver impairment can experience an accumulation of Viramune in their blood, which can cause serious side effects.

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