New Viramune Tablet Approved for Once-Daily Use

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Viramune XR—an extended-release version of nevirapine, a non-nucleoside reverse transcriptase inhibitor (NNRTI)—has been approved by the U.S. Food and Drug Administration (FDA), according to a March 28 announcement from the agency. The new Viramune formulation allows for once-daily dosing, an option that hasn't been recognized by the FDA until now.

According to Jennifer Soares, a Boehringer Ingelheim spokesperson, Viramune XR will likely be available from pharmacies the third week of April.

Immediate-release Viramune, one 200 milligram (mg) tablet taken twice daily, has been the approved dose in the United States since the drug was first approved in 1996. While clinical trials have explored once-daily dosing using the original formulation—two 200 mg tablets once a day—results have been conflicting. Yet, once-daily Viramune is prescribed "off label" by some U.S. health care providers, and it has long been a popular option in other countries.

With the development of Viramune XR (400 mg nevirapine), manufacturer Boehringer Ingelheim set its sight on once-daily approval of the drug in the United States. Approval has now been granted, based on the results of two clinical trials: the VERxVE study, comparing Viramune XR with immediate-release Viramune in first-time treatment takers, and TRANxITION, a study exploring the safety and efficacy of transitioning patients from twice-daily Viramune to once-daily Viramune XR.

VERxVE

This Phase III study randomized 508 treatment-naive individuals to the standard Viramune group (200 mg taken twice daily) and 505 to the Viramune XR group, with patients in both groups also receiving Truvada (tenofovir plus emtricitabine). The average age of participants entering the study was 38, and about 85 percent of the study volunteers were men. About 250 patients were enrolled in the study through European research centers; about 150 were enrolled in the United States; and the remaining patients were enrolled through sites in Latin America or Africa.

Viral loads at study entry were about 50,000 copies, and CD4 counts averaged 228 cells.
Of note, all patients enrolled in the study began treatment with a 14-day lead-in period in which they took one 200 mg tablet of standard Viramune once a day, before starting full dosing—a common practice to reduce the risk of Viramune toxicity upon commencing treatment.

After 48 weeks, a viral load below 50 copies was maintained in 75 percent of patients in the standard Viramune group, compared with 80 percent of patients in the Viramune XR. Virologic failures, including viral load rebounds, were documented in 13 percent of those in the standard Viramune group compared with 11 percent of those in the Viramune XR group.

In patients with pre-treatment viral loads greater than 100,000 copies, according to data presented at the XVIII International AIDS Conference last summer in Vienna, the response rate was 73 percent in the Viramune XR group, compared with 71 in the standard Viramune group. Among patients with pre-treatment viral loads at or below 100,000 copies, the response rate was 79 percent in the standard Viramune group, compared with 86 percent in the Viramune XR group.

The rate of discontinuations due to adverse events in the Viramune XR group was 6.3 percent, compared with 8.9 percent in the standard Viramune group. Symptomatic liver problems were documented in 1.6 percent of Viramune XR–treated patients, compared with 2.8 percent of those taking standard Viramune. Rashes developed in about 8.5 percent of all patients, with no discernable differences between the two groups.

After 48 weeks of treatment, CD4 counts increased an average of 191 cells among those receiving standard Viramune, compared with a 206-cell gain among those receiving Viramune XR.

TRANxITION

Another Phase III study, TRANxITION evaluated the safety and efficacy of switching 443 patients—all with undetectable viral loads—from standard twice-daily Viramune to once-daily Viramune XR. About half the study volunteers were also using Truvada, with the remaining subjects using either Epzicom (abacavir plus lamivudine) or Combivir (zidovudine plus lamivudine). About half the subjects had been using twice-daily Viramune for at least three years.

Two thirds of the patients were switched to once-daily Viramune XR; the remaining third remained on twice-daily standard Viramune.

Twenty-four weeks after transitioning, 94 percent of patients who remained on twice-daily Viramune, compared with 95 percent of patients who switched to Viramune XR, maintained viral loads below 50 copies.

Viramune XR Dosing

There is an increased risk of liver problems in certain people using Viramune when starting HIV treatment for the first time. These liver problems are more likely to occur in women (including pregnant women) with CD4 cell counts greater than 250 at the time of starting treatment. As for men, liver problems are more likely to occur if their CD4 cell count is greater than 400 at the time of starting treatment. In turn, neither standard Viramune nor Viramune XR should be used in patients who meet these CD4 cell criteria.

Even with the approval of Viramune XR, taking the drug remains a two-step process. For the first two weeks (14 days) of treatment, the dose is one 200 mg tablet once a day, which is possible

using the standard formulation of Viramune. Two weeks after starting treatment, the dose of Viramune is increased to one Viramune XR tablet once a day.

Following this schedule—which you should do under your doctor's guidance—can reduce the chance of developing a rash or other side effects.

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