Neuropathy Skin Patch Reduces Pain

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A dermal patch containing the experimental drug NGX-4010 for HIV-related distal sensory polyneuropathy (DSP)—a painful condition caused by nerve damage—significantly reduced pain over a 12-week period, according to the authors of a study published in the June 2008 issue of *Neurology*. These results stand in contrast to a study reported in a February 27, 2008 press release from the drug's developer, NeurogesX, reporting that the patch did not perform better than a control patch in another clinical trial.

DSP may be caused both by HIV and some of the drugs used to treat it, such as Videx (didanosine) and Zerit (stavudine). The nerve damage that occurs can cause alternating tingling and pain, particularly in the extremities such as the feet and hands. Capsaicin, the active ingredient in NGX-4010, is an extract from hot red peppers that has been found to alleviate symptoms of pain.

For the study reported in Neurology, David Simpson, MD, from the Mount Sinai School of Medicine in New York, and his colleagues enrolled 307 people with HIV who had been diagnosed with DSP. They were randomized to apply and wear the full-strength NGX-4010 patch, or a control patch with a small concentration of NGX-4010, for either 30, 60 or 90 minutes.

The patch was worn only once. It was anticipated that patients could have an initial worsening of pain the first few days after the patch was applied, but that patients would report pain reduction in the 2nd to 12th weeks of follow up.

Simpson's team found that a single full-strength NGX-4010 application resulted in an average pain reduction of 22.8 percent, compared with 10.7 percent for those who used the control patch. Moreover, a third of people receiving full-strength NGX-4010 had at least a 30 percent reduction in pain, compared with 18 percent who used the control patch.

Given the uneven results of NGX-4010 in the studies completed thus far, NeurogesX stated in February that it planned to reanalyze the collected data to determine whether approval from the U.S. Food and Drug Administration is possible.