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Ingelheim, Germany, September 21, 2011 – Boehringer Ingelheim announced today that once-daily Viramune® (nevirapine) prolonged-release has received approval for use in the EU. [1] The new, prolonged-release tablet is indicated in combination with other antiretroviral medications for the treatment of HIV-1 infection.

EU approval for the use of one 400 mg tablet once daily for adults and adolescents - and for 50 mg and 100 mg strengths for once-daily treatment of children - is based on results from clinical trials confirming the significant therapeutic benefits of nevirapine when administered in a convenient once-a-day formulation. [2,3]

The Viramune® XR™ single 400 mg tablet once daily was approved in the USA by the Food and Drug Administration (FDA) earlier this year.

In clinical trials, the antiviral efficacy of Viramune® prolonged-release tablets was shown to be non-inferior to the older, twice-daily immediate-release (IR) 200mg tablet, [2,3] with a safety and tolerability profile comparable to nevirapine IR.

SOURCE [1]

Links:
[1] http://www.manufacturing.net//News/Feeds/2011/09/mnet-catch-all-viramune-nevirapine-prolonged-release-once-dail/