

Boehringer Ingelheim International GmbH - 55216 Ingelheim am Rhein

To Health Authorities in countries, which are participating in the Viramune donation program for the prevention of Mother to child transmission

Boehringer Ingelheim  
International GmbH

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## **VIRAMUNE (nevirapine) DONATION PROGRAM**

Boehringer Ingelheim is supporting the distribution of a pouch within the Viramune donation program for use in prevention of Mother-to-Child-Transmission (pMTCT) in resource-limited settings.

Clinical trials have demonstrated that single-dose nevirapine (NVP) is an efficacious, low-cost, and practical therapy for reducing mother-to-child transmission of HIV-1. Efficacy trials relied on a two-dose regime, one dose in tablet form (200 mg) to the mother at the onset of labor and one dose of NVP oral suspension to the newborn after birth. However, administration of the paediatric dose of NVP oral suspension in resource-limited settings has occurred with less success than the maternal dose. The lack of single-dose packaging for NVP oral suspension has been a critical barrier, often preventing provision to HIV+ women at antenatal care visits.

Existing elements of the PMTCT Donations Program (NVP and 1-ml Exacta-Med<sup>®</sup> oral dispenser and cap) could be combined with an appropriately sized, well-sealed, easy-to-use protective foil pouch. This solution addressed the need to improve the protective wrapping (secondary packaging) for NVP oral suspension-filled dispensers being sent home with HIV+ pregnant women in advance of giving birth.

The use of this foil pouch could not improve the shelf life of Viramune oral suspension prefilled by the nurses/physicians in the Exacta Med dispenser.

This foil pouch concerns **only** the donation program, and therefore isn't registered in European Community. The implementation is targeted for July 2007.

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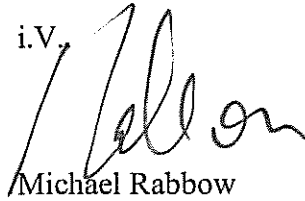
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