

WHO STATEMENT ON ROCHE'S VIRACEPT® RECALL 14 June 2007

ROCHE informed WHO on 8 June 2007 of its global recall of its nelfinavir products (Viracept®), in accordance with European Medicines Agency (EMA) and Swissmedic requirements (except USA, Canada and Japan). The reason for the recall is identification of an impurity in some batches of Viracept®, an antiretroviral (ARV) medicine. The contaminant is a known genotoxic substance. For further information, please see the EMA statement at: <http://www.emea.europa.eu>

Nelfinavir belongs to the Protease Inhibitor (PI) class of antiretroviral medicines. Wherever possible, the PI class should be reserved for second-line therapy, particularly in settings, where availability of ARV formularies is limited. In choosing the PI for second-line therapy for adults and children, a PI boosted by ritonavir (/r) is recommended for antiviral potency.

Current stocks of Viracept® should be quarantined. All remaining Viracept® formulations stock must be returned to Roche. Please contact the Roche country representative for further information about the procedure for return, or Roche headquarters:

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Countries that have included Viracept® in post-exposure prophylaxis packs, should remove and replace it with a suitable boosted protease inhibitor. If no boosted PI are available, dual nucleoside therapy without a PI will remain effective.

Adults or children currently taking Viracept® should not interrupt their antiretroviral therapy. However, they should see their antiretroviral therapy provider as soon as possible, to change from Viracept® to a suitable alternative.

The following protease inhibitors are adequate within-class substitutions for Viracept®: lopinavir/ritonavir (LPV/r), indinavir/ritonavir (IDV/r), saquinavir/ritonavir (SQV/r), atazanavir/ritonavir (ATV/r), and fosamprenavir/ritonavir (FPV/r). LPV/r is the preferred boosted PI, as it has the advantage of being available as a fixed-dose combination and has recently been approved in a new heat-stable formulation, which eliminates the need for refrigeration. In children, SQV is only licensed for use in children over 25kg. ATV and FPV are not yet approved for use in children.

Nelfinavir is sometimes exceptionally used as part of initial therapy for pregnant women. If this is the case and no other PI is available, then substitution of Viracept® by another active ARV from another class of drugs will need to be considered. Non-nucleoside reverse transcriptase inhibitors drugs need to be used with caution in pregnant women.

In summary, for patients needing to substitute Viracept®, options include:

- a boosted protease inhibitor;
- nevirapine – with close observation for toxicity if CD4 is above 250 cells/mm³;
- efavirenz – unless in the first trimester of pregnancy;
- triple nucleoside therapy.

For further details of current WHO HIV/AIDS treatment recommendations, please refer to the following web link: <http://www.who.int/entity/hiv/pub/guidelines/en>.