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# MEDIA RELEASE

FOR IMMEDIATE RELEASE

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## HIV drug linked to serious side effects

People with HIV who are taking the antiretroviral drug darunavir (brand name Prezista, formerly known as TMC-114, distributed by Janssen-Cilag) are being alerted that the drug has been linked to serious liver side effects.

Darunavir is a medication used in combination with ritonavir (Norvir), another antiretroviral medication, to treat adults with HIV infection.

The National Association of People Living with HIV/AIDS (NAPWA) issued the alert today following a statement from Canadian health officials about a small number of cases of serious liver complications, including some deaths, among people taking the drug.

Among patients studied in clinical trials, 0.5 per cent developed hepatitis or inflammation of the liver when taking darunavir. Since the drug's approval in North America, the manufacturer advises that there have been 13 reported cases where patients taking darunavir developed hepatitis, including two who died. A further 25 cases have been reported of patients taking darunavir who developed other liver problems between mid-2006 and the end of 2007, of whom 14 died.

NAPWA stressed that it is not known whether the liver complications were caused by darunavir or were due to other medical problems or medications taken by the affected patients, all of whom had advanced HIV disease, were taking other medications as well, or had illnesses such as hepatitis B or C.

NAPWA warned people taking darunavir to be on the lookout for signs of liver toxicity, and to contact their doctor immediately if they experience any of the following symptoms: dark urine, yellowing of the skin, abdominal pain (especially on the right side below the ribs), general itchiness, decreased appetite, nausea, vomiting or fatigue.

People with pre-existing liver problems (especially hepatitis B or C) are at greater risk of experiencing serious adverse liver events.

NAPWA urges patients taking darunavir not to stop taking the drug unless advised to do so by their doctor, and to contact their doctor if they have any concerns.

**For more details or further comment contact:**

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