

Please return the completed report to:

BC-CfE Pharmacovigilance Initiative, 687-1081 Burrard Street, Vancouver, BC, V6Z 1Y6

Fax: 604-806-9044 Telephone: 604-806-8663

Office use only: BC-CfE #

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Patient Information

First name(s)		Last name		BC-PHN
Sex at birth: <input type="checkbox"/> Male <input type="checkbox"/> Female	Gender identity: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other _____	Height _____ cm	Date of Birth	
		Weight _____ kg	DD _____ MON _____ YYYY _____	

Antiretroviral drugs *suspected* responsible for adverse reaction

Antiretroviral drugs used for Treatment of HIV HIV prevention, Pre-Exposure Prophylaxis (PrEP)

Antiretroviral drug, dose, form (e.g. tablet, liquid)	Start date DD- MON-YYYY	If stopped DD- MON-YYYY

Adverse drug reaction details

Describe symptoms, relevant lab test results

Reaction onset date DD _____ MON _____ YYYY _____

Severity: Mild Moderate Severe Potentially life threatening

Describe Treatment

Hospitalization required?: Yes No

Other possible causes of the reaction (medical conditions, other medications)

Outcome (at time of report):

Reaction is ongoing Reaction has resolved Death date DD _____ MON _____ YYYY _____ Unknown

Reporter information

Name (first, last): Report date: DD _____ MON _____ YYYY _____

Physician Pharmacist Other healthcare provider _____ Other (non-healthcare)

Please indicate if this report has also been submitted to: Health Canada Drug Company

Thank you for reporting Adverse Drug Reactions. See p.2 (back) for additional information

BC-Centre for Excellence in HIV/AIDS (BC-CfE) Pharmacovigilance Initiative

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The Importance of Monitoring Adverse Drug Reactions

Adverse drug reactions ("side-effects") to antiretroviral medications can affect patients' health and interfere with treatment success. Ongoing monitoring of adverse drug reactions is required to detect unexpected toxicities as soon as possible, so health care providers and patients can be warned of new safety concerns. The BC-CfE Pharmacovigilance Initiative collects, evaluates, and analyzes reports of drug toxicity and uses this information to understand and prevent drug-related problems.

Privacy and Confidentiality

Adverse drug reaction reports submitted to the BC-CfE Pharmacovigilance Initiative are handled with the same high level of security as prescriptions for HIV drugs. Information from reports is stored in the BC-CfE Registry, a very secure, computerized database. For more information about privacy and security, refer to the "Patient information sheet for Drug Treatment Program participants" at www.cfenet.ubc.ca.

Information from adverse drug reaction reports is used in the following ways:

- To protect patient safety and support clinical care, a brief summary of the adverse drug reaction is included in the patient's BC-CfE Patient Profile Summary. This summary of antiretroviral treatment history is provided only to health care professionals who are directly involved in a patient's care. Healthcare providers may request a Patient Profile Summary by calling the BC-CfE Drug Treatment Program, telephone 604-806-8515.
- De-identified adverse drug reaction information is used by the Pharmacovigilance Initiative to monitor drug safety. De-identified reports of serious or unexpected reactions are also submitted to the Health Canada Vigilance program, Canada's national drug safety monitoring program. When health information is de-identified, we remove any information which could be used to identify or locate a person (such as name, birth date, personal health number).

**For more information about
Drug toxicities • Safety alerts • Adverse drug reaction reporting
see the BC-CfE website**

bccfe.ca/hiv-drug-safety/