Health Canada Santé Canada

Canadian Adverse Drug Reaction Monitoring Program

Report of suspected adverse reaction due to health products* marketed in Canada

PROTECTED B**
(when completed)

A. Patient Information (See 'Confidentiality' section below)

1. Identifier	2. Age at time of reaction	3. Sex	4. Height	5. Weight
	Year(s)	☐ Male ☐ Female	ft or cm	lbs or kgs

B. Adverse Reaction

1. Outcome attributed to adverse reaction (check all that apply)

- ☐ Death
- ☐ Life-threatening
- ☐ Hospitalization
- ☐ Hospitalization - prolonged
- ☐ Disability
- ☐ Congenital malformation
- ☐ Required intervention to prevent damage/permanent impairment
- ☐ Please specify other

2. Date of reaction	3. Date of this report
YYYY-MM-DD	YYYY-MM-DD

4a. Describe reaction or problem - maximum 3000 characters

4b. Treatment of adverse reaction (medications and/or other therapy, include dates (YYYY-MM-DD)) - maximum 3000 characters

5. Relevant tests/laboratory data (including dates (YYYY-MM-DD)) - maximum 3000 characters

6. Other relevant history, including pre-existing medical conditions (e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction) - maximum 3000 characters

C1. Suspected Health Product(s) (See 'How to report' section below)

Is interaction with another drug suspected?

1. Product Name	Product Strength (mg, mg/mL, etc.)	Manufacturer

2. Dose / Frequency / Route of Administration	3. Therapy dates or duration
	Started: YYYY-MM-DD - Stopped: YYYY-MM-DD **Duration of use**

4. Reason for use of suspected health product	5. Reaction improved after use stopped or dose reduced
	☐ Yes ☐ No ☐ Doesn't apply

6. Lot # (if known)	7. Expiry date (if known)	8. Reaction reappeared if product re-introduced
		☐ Yes ☐ No ☐ Doesn't apply

C2. Concomitant Health Products (List all other health products that the patient was using at the time of the event but which you do not think were involved in the event. - See 'How to report' section below)

1. Concomitant health products - maximum 3000 characters

D. Reporter Information (See 'Confidentiality' section below)

1. Name, address & phone number

2. Occupation	3. Also reported to manufacturer?
Not Specified	☐ Yes ☐ No

Submission of a report does not constitute and admission that medical personnel or the product caused or contributed to the adverse reaction.

*** Use this form to report suspected adverse reactions to pharmaceuticals, biologics (including fractioned blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals.**

**** As per the Treasury Board of Canada Secretariat Government Security Policy.**

HC/SC 4016 (02/05)

Canada

VOLUNTARY ADVERSE REACTION (AR) REPORTING GUIDELINES

Confidentiality of adverse reaction information
Any information related to the identity of the patient and/or the reporter of the AR will be protected as per the Access to Information Act and the Privacy Act. For the « identifier » box, provide some type of identifier that will allow you, the reporter, to readily locate the case if you are contacted for more information; do not use the patients name.

Privacy Notice Statement
Individuals have access to and protection of any provided personal information under the provisions of the Access to Information Act and the Privacy Act. Suspected health product-related AR information is submitted on a voluntary basis, and is maintained in a computerized database. AR information is used for the monitoring of marketed health products, and may contribute to the detection of potential product-related safety issues as well as to the benefit-risk assessments of these products. For more details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; PIB# PPU 088 at: http://infosource.gc.ca/inst/shc/fed07_e.asp**.**

How to report?
All applicable sections of the AR reporting form should be filled in as completely as possible. Complete a separate Web form for each patient. The success of the program depends on the quality and accuracy of the information provided by the reporter.

What to report?
ARs to Canadian marketed health products, including prescription and non-prescription pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and
diagnostic vaccines), natural health products and radiopharmaceuticals are collected
by the Canadian Adverse Drug Reaction Monitoring Program (CADRMP).

All suspected adverse reactions should be reported, especially those that are:

- unexpected, regardless of their severity, i.e., not consistent with product information or labeling; or

- serious, whether expected or not; or

- reactions to recently marketed health products (on the market for less than five years), regardless of their nature or severity.

What is a serious adverse reaction?
A serious AR is one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant
disability or incapacity, is life-threatening or results in death. ARs that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

How to deal with follow-up information for an AR that has already been reported?
Any follow-up information for an AR that has already been reported can be submitted using a new AR reporting form. It can be communicated by telephone, fax, e-mail, or webform to the National AR Centre. In order that this information can be matched with the original report, indicate that it is follow-up information, and enter the case report tracking number provided in the acknowledgement letter. It is very important that follow-up reports are identified and linked to the original report.

Additional information can be faxed to the Adverse Reaction Centre Toll-free 1-866-678-6789.
Please include the Tracking Number included within the Acknowledgement page.

What about reporting ARs to the Market Authorization Holder (manufacturer)?
Health professionals and consumers may also report ARs to the market authorization holder (MAH). Indicate on your AR report sent to Health Canada if a case was also reported to the products MAH.