Health Canada Santé Canada

Canadian Adverse Drug Reaction Monitoring Program

Report of suspected adverse reaction
due to drug products marketed in Canada
(Vaccines excluded)

Health Products and Food Branch
Direction gènèrale des produits de santé et des aliments

- See reverse for return address.
- La version française de ce document est disponible sur demande. Voir au verso pour connaître le centre à contacter.

PROTECTED

A. Patient Information

1. Patient identifier	2. Age at time of reaction	3. Sex	4. Height	5. Weight
	_____ or	☐ Male	_____ feet	_____ lbs
Chart Number	**Date of birth** DD MM YYYY	☐ Female	**or** _____ cm	**or** _____ kgs

B. Adverse Reaction

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

- ☐ Death _____ (dd / mm / yyyy)
- ☐ Life-threatening
- ☐ Hospitalization
- ☐ Hospitalization - prolonged
- ☐ Disability
- ☐ Congenital malformation
- ☐ Required intervention to prevent damage / permanent impairment
- ☐ Other: _____

2. Date and time of reaction DD MM YYYY

3. Date of this report DD MM YYYY

4. Describe reaction or problem

5. Relevant tests / laboratory data (including dates (dd / mm / yyyy)

6. Other relevant history, including preexisting medical conditions
(e.g. allergies, pregnancy, smoking and alcohol use, hepatic / renal dysfunction)

C. Suspected drug product(s)
(See "How to report" section on reverse)

1. Name (give labelled strength & manufacturer, if known).
#1 _____
#2 _____

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1	#1 From (dd / mm / yyyy) - To (dd / mm / yyyy)
#2	#2

4. Indication for use of suspected drug product	5. Reaction abated after use stopped or dose reduced
#1	#1 ☐ Yes ☐ No ☐ Doesn't apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Reaction reappeared after reintroduction
#1 _____	#1 (dd / mm / yyyy) _____	#1 ☐ Yes ☐ No ☐ Doesn't apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't apply

9. Concomitant drugs (name, dose, frequency and route used) and therapy dates (dd / mm / yyyy) (exclude treatment of reaction)

10. Treatment of adverse reaction (drugs and / or therapy), **including dates** (dd / mm / yyyy)

D. Reporter
(See "Confidentiality" section on reverse)

1. Name, address & phone number.

2. Health professional?	3.Occupation	4. Also reported to manufacturer?
☐ Yes ☐ No		☐ Yes ☐ No

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

Canada

Return this form to the address listed for your region

ADVERSE DRUG REACTION (ADR) REPORTING GUIDELINES

Confidentiality of ADR Information
Any information related to the reporter and patient identifiers is kept confidential.

What to report?
An adverse drug reaction (ADR) is a noxious and unintended response to a drug which occurs with use or testing for the diagnosis, treatment or prevention of a disease or the modification of an organic function. This includes **any** undesirable patient effect suspected to be associated with drug use. ADRs as a result of prescription, non-prescription, biological (including blood products), complementary medicines (including herbals) and radiopharmaceutical drug products are monitored. Drug abuse, drug overdoses, drug interactions and unusual lack of therapeutic efficacy are also considered to be reportable as ADRs.

ADR reports are, for the most part, only *suspected* associations. A temporal or possible association is sufficient for a report to be made. Reporting an ADR does not imply a causal link.

ADRs that should be reported include all suspected adverse drug reactions which 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 drugs** (on the market for less than five years) regardless of their nature or severity.

The Canadian Regulations pertaining to reporting ADRs for marketed drug products define a serious adverse drug reaction as "a noxious and unintended response to a drug, which occurs at any dose and 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".

How to report?
To report a suspected ADR for drug products marketed in Canada, health professionals should complete a copy of the **ADR Reporting Form (Report of suspected adverse reaction due to drug products marketed in Canada (Vaccines excluded)** (HC/SC 4016 (04-03)). This form may be obtained from your Regional Adverse Reaction (AR) Centre or from the National Adverse Reaction Centre (see addresses below), and is also available in the Canadian Compendium of Pharmaceuticals and Specialities (CPS). The ADR form is also available at www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/forms/adverse_e.pdf.

Fill in the sections that apply to the report as completely as possible, using a separate form for each patient. Additional pages may be attached if additional space is required. The success of the program depends on the quality and accuracy of the information sent in by the reporter.

Up to two (2) suspected drug products may be reported on one form (#1 = first suspected drug product, #2 = second suspected drug product). Attach an additional form if there are more than two suspected drug products for the reported adverse reaction.

For more information on the ADR monitoring program, additional copies of ADR reporting forms or to report an ADR, physicians, pharmacists and other health professionals are invited to contact the addresses listed for your region.

British Columbia
British Columbia Regional AR Centre
c/o BC Drug and Poison Information Centre
1081 Burrard Street
Vancouver BC V6Z 1Y6
Tel: (604) 806-8625 Fax: (604) 806-8262
adr@dpic.ca

Ontario
Ontario Regional AR Centre
c/o LonDIS Drug Information Centre
London Health Sciences Centre
339 Windermere Road
London ON N6A 5A5
Tel: (519) 663-8801 Fax: (519) 663-2968
adr@lhsc.on.ca

Atlantic
Atlantic Regional AR Centre
For New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland
c/o Queen Elizabeth II Health Sciences Centre
Drug Information Centre
1796 Summer Street, Rm 2421
Halifax NS B3H 3A7
Tel: (902) 473-7171 Fax: (902) 473-8612
adr@cdha.nshealth.ca

Saskatchewan
Saskatchewan Regional AR Centre
c/o Saskatchewan Drug Information Service
College of Pharmacy and Nutrition
University of Saskatchewan
110 Science Place
Saskatoon SK S7N 5C9
Tel: (306) 966-6329 Fax: (306) 966-2286
Sask.AR@usask.ca

Québec
Québec Regional AR Centre
c/o Drug Information Centre
Hôpital du Sacré-Coeur de Montréal
5400, boul. Gouin ouest
Montréal (QC) H4J 1C5
Tel: (514) 338-2961 Fax: (514) 338-3670
pharmacovigilance.hsc@ssss.gouv.qc.ca

All other provinces and territories
National AR Centre
Marketed Health Products Safety and Effectiveness Information Division
Marketed Health Products Directorate
Tunney's Pasture
AL 0701C
Ottawa ON K1A 0K9
Tel: (613) 957-0337 Fax: (613) 957-0335
cadrmp@hc-sc.gc.ca

Health professionals and consumers may also use the following toll free numbers to report adverse drug reactions. Calls will be automatically routed to the appropriate regional or national adverse reaction centre. Telephone : 1-866-234-2345 Fax : 1-866-678-6789

How to deal with follow-up information for an ADR that has already been reported?
Any follow-up information for an ADR that has already been reported can be sent on another ADR form, or it can be communicated by telephone, fax or e-mail if convenient to the appropriate address for your region (see addresses above). So that this information can be matched with the original report, indicate that it is follow-up information, the date of the original report and the report case number if known. It is very important that follow-up reports are identified and linked to the original report.

What about reporting ADRs to the Manufacturer?
Health professionals may also report ADRs to the manufacturer. Indicate on your ADR report sent to Health Canada if a case was also reported to the manufacturer.

For Marketed Health Products Directorate Use Only