



## Consumer Side Effect Reporting Form Canada Vigilance Program

Aussi disponible en français : [www.santecanada.gc.ca/medeffet](http://www.santecanada.gc.ca/medeffet)

PROTECTED WHEN COMPLETED – B\*\*

Complete all mandatory items, marked by a \*, and provide as much information as possible for the remaining items.

### 1. About you – the person reporting the side effect

<b>Last name*</b>	<b>First name*</b>	
<b>Address</b>		
Number – Street	City/Town	Province – Postal Code
<b>Telephone*</b>	<b>Email</b>	

### 2. About the person who had the side effect

<b>Personal Information</b>							
<b>Sex*</b>	<input type="checkbox"/> Male <input type="checkbox"/> Female	<b>Age</b> _____	<input type="checkbox"/> years <input type="checkbox"/> months	<b>Weight</b> _____	<input type="checkbox"/> kg <input type="checkbox"/> lbs	<b>Height</b> _____	<input type="checkbox"/> cm <input type="checkbox"/> feet, inches
<b>Health Information</b>							
Known medical conditions							
Allergies							
Other relevant information (smoking, pregnancy, alcohol use, etc.)							

### 3. About the health product that may have caused the side effect

Health products include prescription and non-prescription medications, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products and radiopharmaceuticals.

If you suspect that more than one health product caused the side effect, attach additional forms/sheets.

<b>Name of product*</b> (For natural health products, list ingredients or attach a copy of the label.)		<b>Manufacturer</b>
<b>DIN/NPN #</b>		<b>Lot #</b>
<b>Expiry date</b> yyyy-mm-dd	<b>Start date</b> yyyy-mm-dd	<b>End date</b> yyyy-mm-dd
<b>Dosage</b>		
Strength (250mg, 1g, etc.)	Quantity (2 tablets, 3 puffs, etc.)	Frequency (twice daily, at bedtime, etc.)
<b>What was the product taken for?</b>	<b>How was the product taken</b> (by mouth, by injection, etc.)?	
<b>Is the product still being taken?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>If the product was restarted, did the side effect return?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not apply		

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



#### 4. About other health products used at the same time

List all products taken around the time of the side effect. Attach additional forms/sheets if necessary.

Name of product	Strength (250mg, 1g, etc.)	Quantity (2 tablets, 3 puffs, etc.)	Frequency (twice daily, at bedtime, etc.)	Reason for taking the product

#### 5. About the side effect

When did the side effect start?      yyyy-mm-dd

When did it stop?                      yyyy-mm-dd

How bad was the side effect? (Select all the boxes that apply)

- |  |   |
|--|---|
| <input type="checkbox"/> Uncomfortable, but did not affect everyday activities | <input type="checkbox"/> Life threatening             |
| <input type="checkbox"/> Bad enough to affect everyday activities              | <input type="checkbox"/> Caused death      yyyy-mm-dd |
| <input type="checkbox"/> Bad enough to be admitted to hospital                 | <input type="checkbox"/> Caused birth defect          |
| <input type="checkbox"/> Caused long term serious disability                   | <input type="checkbox"/> Other                        |

Describe the side effect\* (Also provide available details of lab tests or treatment taken for the side effect, attach additional forms/sheets if necessary.)

How is the person feeling now?

- Recovered    Partially recovered    No change    Getting worse    Other

Have you reported this side effect to the manufacturer of the health product?    Yes    No

#### 6. Send your report by mail OR fax

Canada Vigilance Program  
Marketed Health Products Directorate  
Health Canada  
Postal Locator 0701D  
Ottawa, Ontario K1A 0K9

**Fax:** 1-866-678-6789 (toll-free)  
Prepaid mailing labels are available at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
**For more information** visit us at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect) or  
call us at 1-866-234-2345 (toll-free)

## Instructions to Complete the Consumer Side Effect Reporting Form

### How do I complete the Consumer Side Effect Reporting Form?

- Complete sections 1 to 5 with as many details as you know. You may use additional forms/sheets if there is not enough space.
- Your pharmacist, doctor or other health professional can provide information that will help you complete your report.

### What information do I need to know when filling out the form?

#### Section 1 – About you - the person reporting the side effect.

- Include the name and contact details of the person completing the form.
- Contact information is necessary in case we need more information to assess the report.
- Identity of the person reporting a side effect remains confidential and is protected under the *Privacy Act*.

#### Section 2 – About the person who had the side effect.

- Do not provide information that will identify the person who had the side effect (name, identifying numbers, etc.).
- Include any medical history and other information that you believe may help in the assessment of the side effect.

#### Section 3 – About the health product that may have caused the side effect.

- Include all details about the product(s) you suspect may have been the cause of the side effect.
- Provide exact name of the health product, including abbreviations such as SR, XR, etc.
- The DIN/NPN refers to the Drug Identification Number/Natural Product Number and is generally found on the product label or packaging. This number makes it easy to identify the exact product.
- If you suspect more than one product has caused the side effect, provide the additional information on a separate sheet.
- A person who has experienced a side effect should consult a health care practitioner about whether to continue using/restart the product.

#### Section 4 – About other health products used at the same time.

- Include details about all health products being taken when the side effect occurred (includes prescription and non-prescription as well as natural health products). The side effect experienced may have been caused by other health products than the one suspected or by the combination of products.

#### Section 5 – About the side effect.

- Provide as much information as possible to describe the side effect experienced, including dates involved, symptoms experienced and their severity.
- A serious or life threatening disability may include loss of physical strength or mobility, vision, speech or hearing impairment, etc.
- Include, if available, results of laboratory tests (e.g. blood and urine tests or bone density scans).
- Describe available details of treatment taken for the side effect (allergy medication, pain relievers, etc.).

#### Section 6 – Send us your report by mail or fax.

- Before sending, review the form to ensure you have not missed any important information.
- Be sure to include both pages of the form, all additional forms/sheets and other relevant documents when sending your report.
- A postage paid mailing label is available on MedEffect™ Canada Web site at: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect) or by calling 1-866-234-2345 (toll-free).
- Reports can be faxed to: 1-866-678-6789 (toll-free) or mailed to:  
Canada Vigilance Program  
Marketed Health Products Directorate  
Health Canada  
Postal Locator 0701D  
Ottawa, Ontario K1A 0K9

### What is a side effect?

Side effects, also known as adverse reactions, are troublesome symptoms or feelings that occur when taking a health product. They can range from minor irritations, such as a skin rash, to serious and life-threatening reactions, such as a heart attack or liver damage. A side effect can also be when a product has no effect or has not performed the intended treatment. They can occur within minutes after taking a medicine, or can take years to develop.

### What to report?

Suspected side effects to any health product, whether it was prescribed by your health professional or bought without a prescription, should be reported. Health products include prescription and non-prescription medications, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products and radiopharmaceuticals. Fractionated blood products, such as albumin, plasma derived clotting factors and immune globulins, are blood products that have undergone a manufacturing process and have a Drug Identification Number (DIN). Radiopharmaceuticals are drugs either of chemical or biological origin which are intentionally made radioactive for the purpose of diagnosing illness and are always prepared and given by a health professional.

You can report side effects that have happened:

- to you personally;
- to your child or other people you're responsible for; or
- someone who asks you to make a report on their behalf.

### When to report?

Side effects should be reported as soon as possible, especially if they interfere with everyday activities or if they are not mentioned in the information supplied with the health product.

### Why report a side effect?

All health products have benefits and risks. Although health products are carefully tested before they are licensed for sale in Canada, some side effects may become evident only after a product is in use by the general population.

When you report a side effect to the Canada Vigilance Program, the information from your report, along with other information, is used to check for new safety concerns about a product. As a consumer, your report contributes to improving the safety and safe use of health products for everyone.

### Can I report a side effect without filling out the form?

You can also report side effects to health products to the Canada Vigilance Program:

- Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- By calling **1-866-234-2345** (toll-free)

**NOTE:** *If you are currently suffering from a side effect to a drug or health product, contact your health professional or local health authorities. The Canada Vigilance Program does not provide medical advice.*

### Protecting your personal information

On the form, we ask for the name and contact details of the person reporting the adverse reaction. This is so we can get in touch if we need more information. When providing information about the person who had the suspected adverse reaction, do not include the patient's name. Personal information collected, used or disclosed under the Canada Vigilance Program is confidential and protected. For the purposes of the Canada Vigilance Program, information related to the identity of a patient and/or reporter of the adverse reaction will be protected as personal information under the *Privacy Act*, and under the *Access to Information Act* in the case of an access to information request. For details about personal information collected under this program, visit the Government of Canada web site on Institution-Specific Personal Information Banks under Health Canada, Health Products and Food Branch, Branch Incident Reporting System, PIB # ppu 088 at: <http://infosource.gc.ca/inst/shc/fed07-eng.asp> (Health Products and Food Branch, Branch Incident Reporting System).