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# Canadian Adverse Reaction Newsletter

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www.healthcanada.gc.ca/carn

## In this issue



## Scope

This quarterly publication alerts health professionals to potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to stimulate adverse reaction reporting as well as to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk–benefit evaluations and regulatory decisions are undertaken. The continuous evaluation of health product safety profiles depends on the quality of your reports.

## Reporting Adverse Reactions

**Canada Vigilance Program**
Phone: 866 234-2345
Fax: 866 678-6789
Online: www.healthcanada.gc.ca/medeffect

## Did you know?

To receive the Newsletter and health product advisories free by email, subscribe to the MedEffect™ e-Notice at www.healthcanada.gc.ca/medeffect

# Intravenous immune globulin (IVIG): hemolytic reactions

### Key points

- Hemolysis is a rare adverse reaction (AR) resulting from the use of intravenous immune globulin (IVIG).
- A standardized case definition of IVIG-associated hemolysis has been proposed to assist in the investigation and reporting of suspected cases.
- In an analysis of AR cases by Health Canada using this definition, risk factors for hemolysis included blood group A or AB and a high total dose of IVIG (≥ 2 g/kg).

Canada is one of the world's highest per capita users of intravenous immune globulin (IVIG).[1] Since 1998, the Canadian Blood Services has reported a steady increase in the use of IVIG of 11.3% per year on average.[2] In the context of this increasing use, it is important for health care professionals to be aware of hemolysis,* a rare but well-described adverse reaction (AR) associated with IVIG therapy. Product monographs for IVIG products on the Canadian market provide information on the risk of hemolysis.[4–6] In February 2009, criteria for a standardized case definition of IVIG-associated hemolysis were proposed by Héma-Québec and the Canadian Blood Services through the IVIG Hemolysis Pharmacovigilance Group "to assist in the investigation and reporting of suspected cases" (Table 1).[7,8]

The primary constituent of IVIG is concentrated IgG made from large pools of human plasma. Several commercial brands of the product have been authorized for use in Canada as replacement therapy in cases of primary and secondary immune deficiencies and for idiopathic thrombocytopenic purpura. Some are also authorized for the treatment of chronic inflammatory demyelinating polyneuropathy.[4–6,9] IVIG is also being used off-label for a growing number of conditions.[10]

Using the case definition developed by the IVIG Hemolysis Pharmacovigilance Group, Health Canada analyzed all reports of hemolysis (reported as hemolytic anemia, hemolysis, spherocytic anemia, hemolytic reaction, decreased hemoglobin and hemolytic transfusion reaction) suspected of being associated with the use of IVIG that were received from Dec. 1, 2006, to Mar. 31, 2009. Of the 81 reports received, 20 involved cases that met the criteria for IVIG-associated hemolysis, 23 had an alternate possible cause for anemia, and 38 lacked the required laboratory work

*Alteration, dissolution or destruction of red blood cells in such a manner that hemoglobin is liberated into the medium in which the cells are suspended (e.g., by specific complement-fixing antibodies, toxins, various chemical agents, tonicity, alteration of temperature).[3]

(32 of the 38 also had an alternate possible cause, 4 of which had a negative result of a direct antiglobulin test).

Table 2 (page 3) provides an analysis of the 20 cases that met the definition of IVIG-associated hemolysis. Nine of the 20 patients received IVIG for labelled indications and 11 for off-label indications. The total dose ranged from 35 to 500 g. Patient age ranged from 7 months to 86 years. The number of men and women in the AR reports was equal; however, the patient exposure to IVIG is not known. The reported onset of hemolysis ranged from the day of IVIG infusion to 2 weeks afterwards. Hemoglobin levels dropped by 28 to 78 g/L (mean decrease 46 g/L, median 44 g/L).

Risk factors for hemolysis, as noted by the IVIG Hemolysis Pharmacovigilance Group,[7,8] included blood group A (in 14 cases) or AB (in 6 cases) and a high total dose of IVIG (≥ 2 g/kg). Of the AR reports that included the total dose in grams per kilogram, 85% of the patients (11/13) received a total dose of ≥ 2 g/kg.

Health care professionals are encouraged to report to Health Canada ARs suspected of being associated with the use of IVIG and to include any available information relevant to hemolysis.

Table 1: Criteria for the standardized case definition of hemolysis associated with the use of intravenous immune globulin (IVIG), as developed by the IVIG Hemolysis Pharmacovigilance Group*[7,8]

| Variable | Definition |
|---|---|
| Onset | • Within 10 days of IVIG administration† |
| Laboratory signs | • Drop in hemoglobin of ≥ 10 g/L |
| | • Positive result of direct antiglobulin test‡ |
| | • At least 2 of:<br>- increased reticulocyte count<br>- increased lactate dehydrogenase level<br>- low haptoglobin level<br>- unconjugated hyperbilirubinemia<br>- hemoglobinemia<br>- hemoglobinuria<br>- presence of significant spherocytosis |
| Exclusion criteria | • History or examination consistent with an alternate cause of anemia, including blood loss, other drug-induced hemolysis, anemia associated with chemotherapy for cancer, or hemolysis associated with an underlying disease |
| | • Negative result of direct antiglobulin test |
| | • Absence of other inclusion criteria, in particular evidence of hemolysis |

*Héma-Québec and the Canadian Blood Services are members of the group.
†Cases detected more than 10 days after treatment should also be reported when it is considered likely that the hemolytic process started within 10 days after treatment.
‡Also known as direct Coombs test or DAT.

Elaine Taylor, MD, Health Canada

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## Antiviral medications and influenza A (H1N1): reporting adverse reactions

Reports of adverse reactions to antiviral medications are important. This information will be used to guide the safe and effective use of these drugs, particularly in certain patient groups (e.g., pregnant women and children < 1 year of age) for which only limited safety data may be available. Health care professionals are encouraged to report any suspected adverse reaction involving an antiviral medication to the Canada Vigilance Program:

- by **calling** toll-free at 1-866-234-2345
- by reporting **online** at www.healthcanada.gc.ca/medeffect
- by **completing a form** that you can send by:
  - postage-paid mail or
  - fax toll-free to 1-866-678-6789

The form and postage-paid label are available at **www.healthcanada.gc.ca/medeffect** or by calling **1-866-234-2345**.

Table 2: Summary of 20 reports of hemolysis suspected of being associated with IVIG that were submitted to Health Canada from Dec. 1, 2006, to Mar. 31, 2009, and that met the proposed case definition of IVIG-associated hemolysis*[7,8]

| Case | Patient age/sex | Blood group | Product and dose | Indication | Time to onset† | Drop in hemoglobin, g/L | Intervention/outcome |
|---|---|---|---|---|---|---|---|
| 1 | 67/F | A | IGIVnex 90 g/d x 2 days; total dose 180 g | Idiopathic thrombocytopenic purpura (ITP) | 1 day | 32 | Blood transfusion; recovered without sequelae |
| 2 | 67/M | A | Gamunex/IGIVnex on days 1, 2, 3, 4, 5 and 12; total dose unknown | Chronic inflammatory demyelinating polyneuropathy (CIDP) | 7 days | 28 | Unknown |
| 3 | 60/M | A | Gamunex 40 g/d x 5 days; total dose 200 g (2 g/kg) | Guillain–Barré syndrome‡ | About 1 day | 51 | Unknown |
| 4 | 86/F | AB | Gamunex/IGIVnex 25 g/d x 5 days; total dose 125 g | Guillain–Barré syndrome‡ | 8 days | 50 | Unknown |
| 5 | 13/F | AB | IGIVnex 55 g/d x 2 days; total dose 110 g (2 g/kg) | Multiple sclerosis‡ | 1 day | 56 | Recovered without sequelae |
| 6 | 58/F | A | Gamunex 160 g over 2 days; total dose 160 g (2 g/kg) | ITP | 3 days | 50 | Blood transfusion; prolonged hospitalization; recovered without sequelae |
| 7 | 7 mo/M | AB | Gamunex 17.5 g/d on days 1 and 3; total dose 35 g | Kawasaki disease‡ | 3 days | 35 | Blood transfusion; recovered without sequelae |
| 8 | 8/F | A | Gamunex 155 g over 8 days; total dose 155 g | Kawasaki disease‡ | 7 days | 41 | Involved or prolonged hospitalization; outcome unknown |
| 9 | 64/F | A | Gamunex/IGIVnex 42.5 g/d x 3 days; total dose 127.5 g (1.5 g/kg) | Guillain–Barré syndrome‡ | 3 days | 70 | Blood transfusion; recovered |
| 10 | 18/M | A | Gamunex 1g/kg daily x 2 days; total dose 170 g (2 g/kg) | ITP | Following infusion | 32 | Unknown |
| 11 | 69/M | AB | IGIVnex 80 g/d on days 1 and 4; total dose 160 g | Myasthenia gravis‡ | 7 days | 56 | Blood transfusion; prolonged hospitalization; outcome unknown |
| 12 | 3/M | A | Gamunex/IGIVnex 27.5 g/d on days 1 and 4; total dose 55 g (3.9 g/kg) | Kawasaki disease‡ | 5 days | 32 | Involved or prolonged hospitalization; recovered without sequelae |
| 13 | 85/M | AB | Gamunex/IGIVnex 0.4 g/kg daily x 5 days; total dose 175 g (2.1 g/kg) | Myasthenia gravis‡ | 8 days | 66 | Blood transfusion; prolonged hospitalization; recovered without sequelae |
| 14 | 76/F | A | Gamunex/IGIVnex 1 g/kg; total dose unknown | ITP | Same day | 29 | Blood transfusion; outcome unknown |
| 15 | 74/M | A | Gamunex 27.5 g/d x 5 days; total dose 137.5 g (2.18 g/kg) | ITP | 3 days | 31 | Death (not related) |
| 16 | 42/M | A | Gamunex 100 g/d on days 1, 2, 7, 13 and 15; total dose 500 g (5.05 g/kg) | ITP | 5 days | 40 | Involved or prolonged hospitalization; recovered without sequelae |
| 17 | 57/M | A | Gamunex 150 g over 2 days; total dose 150 g (2 g/kg) | Renal transplant rejection‡ | Within 2 weeks of treatment | 39 | Blood transfusion; recovered without sequelae |
| 18 | 23/F | AB | Gammagard liquid 100 g/d on days 1, 2 and 4; total dose 300 g | Possible Guillain–Barré syndrome,‡ facial weakness (not yet diagnosed) | 4–14 days | 78 | Blood transfusion; prolonged hospitalization; recovered without sequelae |
| 19 | 59/F | A | Gamunex 0.4 g/kg x 5 days; total dose 137.5 g (2.1 g/kg) | CIDP | 6–10 days | 49 | Blood transfusion; hospitalization; outcome unknown |
| 20 | 17/F | A | IGIVnex 70 g/d x 2 days; total dose 140 g (2.4 g/kg) | ITP | 6 days | 48 | Blood transfusion; recovered without sequelae |

*These data cannot be used to determine the incidence of adverse reactions (ARs) because ARs are underreported and neither patient exposure nor the amount of time the drug was on the market has been taken into consideration.
†Estimated from the beginning of the treatment.
‡Off-label indication.

# Sildenafil (Revatio) and medication incident

## Key points

- Health Canada received a report of a medication incident related to sildenafil (Revatio) and drug-name confusion.
- An emergency physician did not recognize Revatio as a brand of sildenafil (also marketed as Viagra) and initiated intravenous nitroglycerin therapy, which could have led to a potentially life-threatening reaction.
- This case demonstrates that dual brand names for a single drug may pose particular risks for errors.

In December 2008, Health Canada received a report of a medication incident related to Revatio and confusion over the drug's brand name. A medication incident is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[1]

A woman in her mid-50s sought care at an emergency department after experiencing chest pain. She had a history of primary pulmonary hypertension (PPH), and her medications included Revatio (sildenafil citrate). Following an electrocardiogram, the patient was given acetylsalicylic acid and sublingual nitroglycerin for treatment of cardiac ischemia. Intravenous nitroglycerin therapy was then started for continued chest pain and an elevated troponin T level. The emergency physician had reviewed the patient's medication list but did not recognize Revatio as a brand of sildenafil. An internist saw the patient shortly thereafter, realized the potential problem and stopped the nitroglycerin therapy. The patient experienced no adverse effects.[2]

The use of nitrates regularly or intermittently in any form (e.g., oral, sublingual, transdermal, by inhalation) is contraindicated in patients taking sildenafil citrate because of the risk of potentially life-threatening hypotension.[3,4] A similar contraindication exists for other selective phosphodiesterase-inhibiting drugs such as vardenafil hydrochloride (Levitra) and tadalafil (Cialis).[5,6] Sildenafil citrate is also marketed as Viagra for erectile dysfunction and is usually prescribed in 50-mg doses to be taken as needed about 30 to 60 minutes before sexual activity.[3] Revatio is indicated for the treatment of PPH, usually in 20-mg doses to be taken 3 times daily.[4]

Dual brand names for a single drug may pose particular risks for error when one of the products' names is much less widely recognized, as in this example. Practitioners are well aware of the brand name Viagra and its contraindications. However, the name Revatio is likely not as well recognized, particularly among those unfamiliar with the management of PPH. Patients with PPH may also present with concomitant coronary artery disease, increasing the risk of receiving a nitrate.[2] The potential severity of the drug interaction between nitrates and sildenafil indicates a heightened risk of significant patient harm should an error occur.

A number of drugs available on the Canadian market have dual brand names. Medication incidents have been documented with some of these products. For example, patients have received duplicate therapy when the same medication is available under more than one brand name.[2,7]

Health care professionals are encouraged to include the generic names of medications when documenting, reviewing or sharing patient medication histories. Drug references should be consulted for unfamiliar names of health products. Patients or caregivers can be active participants in the prevention of errors by becoming familiar with both the brand and generic names of all medications they are taking. They should also document both names on an up-to-date list. Health care professionals should report all medication incidents, including near misses, to the Institute for Safe Medication Practices Canada (www.ismp-canada.org/cmirps.htm) and suspected adverse reactions to the Canada Vigilance Program (www.healthcanada.gc.ca/medeffect; tel 866 234-2345).

Sally Pepper, BSc Phm; Barry Jones, BPharm (Hons) MPS, Health Canada

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Health Canada / Santé Canada

# Canada Vigilance

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

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

The form should be printed and faxed toll free to:
**1 866 678-6789** or mailed as per instructions provided.

**PROTECTED B****
**(when completed)**

La version française de ce document est disponible à: http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-fra.php

## A. Patient Information (See " Confidentiality" section)

| 1. Identifier | 3. Sex | 4. Height | 5. Weight |
|---|---|---|---|
| 2. Age at time of reaction | ☐ Male ☐ Female | _____ feet or _____ cm | _____ lbs or _____ kgs |

## B. Adverse Reaction

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

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

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

**4. Describe reaction or problem**

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

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

## C. Suspected Health Product(s) (See "How to report" section)

**1. Name** (give labeled strength & manufacturer, if known)
# 1
# 2

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

| 4. Indication for use of suspected health 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 (yyyy/mm/dd) | # 1 ☐ Yes ☐ No ☐ Doesn't apply |
| # 2 | # 2 | # 2 ☐ Yes ☐ No ☐ Doesn't apply |

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

**10. Treatment of adverse reaction** (medications and / or other therapy), **include dates** (yyyy/mm/dd)

## D. Reporter Information (See " Confidentiality" section)

**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.

*** Use this form to report suspected adverse reactions to pharmaceuticals, biologics (including fractionated 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 (10/08)

Canada

Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined.
Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

## Quarterly summary of health professional and consumer advisories

(posted on Health Canada's website: June 2, 2009 – Aug. 21, 2009)

| Date | Product | Subject |
|---|---|---|
| Aug 20 | Tumour necrosis factor (TNF) blockers | Update — risk of cancer in children and young adults |
| Aug 19 | Foreign products | Alerts — Clarcon skincare products; Delima Raja Urat and Cao Gen Bai Lin Wan; New Whey liquid products; Stamina-Rx |
| Aug 14 & 20 | Plavix (clopidogrel) | Potential interaction with proton pump inhibitors |
| Aug 13 | Xolair (omalizumab) | Update — increased risk of cardiovascular problems |
| Aug 7 | Buying drugs online | Update — risks of buying drugs online |
| Aug 5 & 6 | Medtronic Paradigm Quick-set Infusion Sets | Recall on lot 8 |
| July 29 | Foreign products | Alerts — Air Ikan Haruan; XP Tongkat Ali Supreme; Neovidan |
| July 28 & Aug 5 | Oral sodium phosphate products | Products no longer authorized for purgative use |
| July 24 | Dophilus Chewable Tablets | Warning — milk allergy risk |
| July 17 | Telzir (fosamprenavir) | Potential increased risk of myocardial infarction |
| July 10 | Specific-Formula Arthro-Ace | Warning — unauthorized health product |
| July 9 | Lantus (insulin glargine) | Update — ongoing safety review |
| July 4 | Hardcore Energize Bullet | Warning — unauthorized energy drink |
| June 29 | Foreign products | Alerts — Slimbionic, Xsvelten, Herbal Xenicol, BioEmagrecim; 999 Fitness Essence; Libimax; 24" ince, Light Some, Paiyouji, Pearl White Slimming, Reducing Weight Easily |
| June 26 | pms – Phenobarbital (60 mg) | Recall — risk of accidental overdose |
| June 25 | Piroxicam | Updated labelling — drug no longer to be used for acute pain or inflammation |
| June 24 | Nutural Slim | Warning — unauthorized weight loss product |
| June 22 | HIV Home Test Kit | Unlicensed medical device |
| June 18 | Foreign product | Alert — Levemir insulin |
| June 17 | Foreign products | Alert — Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Swabs and Zicam Cold Remedy Swabs, Kids Size |
| June 11 | Raptiva (efalizumab) | Market withdrawal |
| June 10 | Iron-containing products | Important labelling information |
| June 4 | Slim Magic Herbal | Warning — unauthorized weight loss product |
| June 3 | CellCept (mycophenolate mofetil) | Potential risk of pure red cell aplasia |
| June 3 | Foreign products | Alerts — Fangocur Mineral Drink; Jia Yi Jian, Fortodol; Shan Dian Qiang Xiao Shou; Zencore Plus; Zhong Guo Shen Fang |
| May 18 | Implantable pulse generators | Important safety information — Kappa and Sigma series |

Advisories are available at www.healthcanada.gc.ca/medeffect.


# Canadian Adverse Reaction Newsletter

Health Canada
Marketed Health Products Directorate
AL 0701C
Ottawa ON K1A 0K9
Tel: 613 954-6522
Fax: 613 952-7738

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Alanna Maloney, BHSc
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### Suggestions?

Your comments are important to us. Let us know what you think by reaching us at mhpd_dpsc@hc-sc.gc.ca

### Reporting Adverse Reactions

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