

ALERT: Revatio is Another Brand Name for Sildenafil

By Christine Koczmara, RN, BSc, Sylvia Hyland, BScPhm, MHSc (Bioethics), and Julie Greenall, BScPhm, MHSc (Bioethics)

Abstract

In this column, the authors highlight a medication incident that occurred with Revatio (sildenafil), along with the learnings and recommendations from a previously published ISMP Canada Safety Bulletin.

It is well-known to health care practitioners that use of nitroglycerin therapy is contraindicated in patients taking sildenafil (commonly known as Viagra). Many health care practitioners may be unaware that *sildenafil is also marketed under the brand name Revatio* for treatment of primary pulmonary hypertension or pulmonary hypertension secondary to connective tissue disease. The following incident signals the need to heighten the awareness that Revatio is a brand name for sildenafil.

Medication incident

A woman in her mid-50s presented to an emergency department with chest pain. An electrocardiogram revealed some ST-T wave changes that were strongly suggestive of cardiac ischemia. The patient's medical history included primary pulmonary hypertension, and her medications included Revatio. Although the patient's home medication list was documented and reviewed, nitroglycerin, among other medications, was ordered for the patient, initially for sublingual administration and then for intravenous administration, for her continuing chest pain and elevated serum troponin T. Fortunately, the patient was also seen by an internist shortly thereafter. This physician recognized Revatio as a brand name for sildenafil. The emergency physician was immediately informed and the nitroglycerin was discontinued. The patient experienced no adverse effects.

Recent therapy with any brand of sildenafil (Viagra, Revatio) is an absolute contraindication to initiation of any nitrate, in any form (e.g., oral, sublingual, transdermal, by inhalation, or intravenous) because there is a risk of potentially life-threatening hypotension (Pfizer Canada, 2009). This contraindication is echoed in product monographs for other selective phosphodiesterase-inhibiting drugs available in Canada, such as tadalafil (Cialis) (Eli Lilly, 2008) and vardenafil (Levitra) (Bayer, 2008).

Contributing factors

The following factors were identified as potentially contributing to this incident:

- Exclusive use of the brand name Revatio on the patient's medication list (without mentioning the generic name, sildenafil).

- Practitioners, although knowledgeable about the different indications for sildenafil, were not aware that the drug had more than one brand name.
- The urgency of the situation (i.e., patient with ischemic chest pain) and the lack of readily available drug references at the point of care led practitioners to omit the step of consulting drug references for pertinent information about Revatio.
- Lack of drug interaction screening.

Recommendations

To minimize the potential occurrence of an incident similar to the one described above, the following recommendations are suggested. (Some of these strategies may also be applicable to Emergency Medical Services where practitioners can administer nitroglycerin as part of a medical directive).

Facilities and practitioners

- When documenting (or reviewing) a patient's list of home medications, include and ensure that the generic name of every drug is charted.
- Consider including prompts in processes and tools (e.g., cardiac assessment forms and applicable order sets) to verify that the patient, regardless of gender or age, has not recently used a phosphodiesterase-inhibiting drug.
- Check drug references for unfamiliar drug products. Readily available access to a pharmacist can assist with this process.
- Consider making electronic drug information references available to health care providers at the point of care. With thousands of medications on the market (and each drug entity having at least one brand name) and many new drugs coming onto the market each year, ready access to up-to-date drug information is essential for safe medication use. For example, electronic drug references are available for use with personal hand-held devices at the point of care.
- Assess opportunities for automated system-based alerts to warn practitioners about potentially lethal drug combinations before medication administration. For example, facilities with automated dispensing cabinets or computerized prescriber order entry systems could develop on-screen alerts requiring the practitioner to confirm, when considering use of a nitrate medication, that the patient has not received or taken one of the selective phosphodiesterase-inhibiting medications.

Community pharmacies, physicians' offices, and outpatient clinics

- Ensure that all medication information available to patients and shared with other practitioners includes the generic name. For example, community pharmacies should consider reviewing how the generic name is presented on labels for medications dispensed, in drug information documents provided to patients, and on medication profiles that may be provided to patients or shared with other institutions or health care practitioners.

- Engage patients in the medication use process by educating them about the medications they are taking, assisting them to maintain an up-to-date list of medications with both generic and brand names for each drug, and encouraging them to provide the list to health care practitioners whenever they access health care services.
 - Information on Revatio directed towards consumers is available from the manufacturer and can be used to educate patients (Pfizer, 2008).

The individual practitioner who reported this incident was the physician who prescribed the nitroglycerin. The report eloquently conveyed the concern that, unlike Viagra and other selective phosphodiesterase-inhibiting medications, Revatio is not a well-known brand name. Although other generic medications may be marketed under different brand names for different indications by one manufacturer, *the potential severity of the drug interaction between nitroglycerin, a commonly used medication for the treatment of chest pain (ACC/AHA, 2007; Bassand et al., 2007) and Revatio (sildenafil) makes this a particularly high-risk situation.*

ISMP Canada has notified Pfizer, the manufacturer of both Viagra and Revatio, of this incident. In addition, ISMP Canada has alerted Health Canada about this report.

This article was written using materials from ISMP Canada, with permission (ISMP Canada Safety Bulletin. January 13, 2009. 9(1), 1–2. Available from: <http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2009-1ALERTRevatioMedicationIncident.pdf>).

ISMP Canada gratefully acknowledges the valuable lessons learned and information reported by professionals in the Canadian healthcare community that can then be shared to enhance medication system safety. All ISMP Canada Safety bulletins are available from <http://www.ismp-canada.org/ISMPCSafetyBulletins.htm>.

ISMP Canada is an independent national not-for-profit organization committed to the advancement of medication safety in all health care settings. ISMP Canada maintains a national voluntary medication incident and ‘near miss’ reporting program founded for the purpose of sharing the learning experiences from medication errors. Our collaborative goal is implementation of preventive strategies and system safeguards to decrease the risk for error-induced injury.

ISMP Canada is a key partner in the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

Medication Incidents (including near misses) can be reported to ISMP Canada:

- through the website http://www.ismp-canada.org/err_report.htm or**
- by phone: 416-733-3131 or toll free: 1-866-544-7672.**

ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

About the authors

Christine Koczmara, RN, BSc, is a senior medication safety analyst with the Institute for Safe Medication Practices Canada (ISMP Canada). She also holds a casual position as a bedside nurse in an intensive care unit (ICU).

Sylvia Hyland, BScPhm, MHSc (Bioethics), is Vice-President and Chief Operating Officer of the Institute for Safe Medication Practices Canada (ISMP Canada), Toronto, Ontario.

Julie Greenall, BScPhm, MHSc (Bioethics), is a Project Leader with the Institute for Safe Medication Practices Canada. She also holds a casual position as a staff pharmacist in a community hospital.

Contact:

Christine Koczmara: ckoczmara@ismp-canada.org

Sylvia Hyland: shyland@ismp-canada.org

Julie Greenall: jgreenall@ismp-canada.org

References

- American College of Cardiology/American Heart Association. (2007). 2007 guidelines for the management of patients with unstable angina/non ST-elevation myocardial infarction: A report of the American College of Cardiology/American Heart Association task force on practice management of patients with unstable angina/ non ST-elevation myocardial infarction [Electronic version]. **Journal of the American College of Cardiology**, **50**(7), e31-e157. Retrieved March 9, 2008, from <http://content.onlinejacc.org/cgi/reprint/50/7/e1>
- Bassand, J.P., Hamm, C.W., Ardissino, D., Boersma, E., Budaj, A., Fernandez-Aviles, F., et al. (2007). Task force for diagnosis and treatment of non-ST-segment elevation acute coronary syndromes of European Society of Cardiology. Guidelines for the diagnosis and treatment of non-ST-segment elevation acute coronary syndromes [Electronic version]. **European Heart Journal**, **28**, 1598–1660. Retrieved March 9, 2009, from <http://eurheartj.oxfordjournals.org/cgi/reprint/28/13/1598>
- Bayer Inc. (2008). **Levitra (vardenafil hydrochloride tablets)** (product monograph) [Electronic version]. Toronto: Bayer Inc. Retrieved March 9, 2009, from Health Canada Drug Product Database from <http://205.193.93.51/dpdonline/displayInfo.do?drugCode=kmToWxdEso1%3D>
- Eli Lilly Canada. (2008). **Cialis (tadalafil tablets)** (product monograph) [Electronic version]. Toronto: Eli Lilly Canada. Retrieved March 9, 2009, from http://www.lilly.ca/searchable/pm/docs/08_Cialis%20PM_15Apr2008_MK.pdf
- Pfizer Canada Inc. (2009). **Revatio, sildenafil citrate tablets** (product monograph) [Electronic version]. Kirkland, QC: Pfizer Canada Inc. Retrieved March 9, 2009, from <http://www.pfizer.ca/english/our%20products/prescription%20pharmaceuticals/default.asp?s=1&id=31&doc=enmonograph>
- Pfizer Canada Inc. (2008). **Revatio, sildenafil citrate tablets. Part III: Consumer information** (product monograph) [Electronic Version]. Kirkland, QC: Pfizer Canada Inc. Retrieved March 9, 2009, from <http://www.pfizer.ca/english/our%20products/prescription%20pharmaceuticals/default.asp?s=1&id=31&doc=enpatient>