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Canadian Adverse Reaction Newsletter

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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

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Pregabalin (Lyrica): suicidal ideation and attempt

Key points

- Health Canada received 16 reports of suicidal ideation and 1 report of suicide attempt suspected of being associated with the use of pregabalin (Lyrica).
- The Canadian product monograph for Lyrica lists suicide attempt under "less common clinical trial adverse drug reactions" and describes it as being infrequent.
- Seven of the 16 cases included a positive dechallenge, and 1 case included a positive rechallenge.

Pregabalin (Lyrica) has analgesic, antiepileptic and anxiolytic activity.[1] Marketed in Canada since July 2005, pregabalin is indicated for the management of neuropathic pain associated with diabetic neuropathy, postherpetic neuralgia and pain associated with fibromyalgia in adults, and it may be useful in the management of central neuropathic pain. The Canadian product monograph for Lyrica lists suicide attempt under "less common clinical trial adverse drug reactions" and describes it as being infrequent.[1]

From the date of marketing to Dec. 15, 2009, Health Canada received 16 reports of suicidal ideation and 1 report of suicide attempt suspected of being associated with the use of pregabalin (Table 1). Five cases are not described in the table because the reports contained limited information. One of these 5 cases reported a suicide attempt by a patient also taking opioids. Seven of the 16 cases included a positive dechallenge (abatement of symptoms of suicidality upon stopping or reducing the dosage of pregabalin) and one case included a positive rechallenge (reappearance of symptoms after reintroduction of pregabalin). Confounders identified in some of the cases included psychiatric disorders, history of depression and suicidal ideation, post-traumatic stress disorder and use of psychotropic medications. Patients with chronic pain are at increased risk of depression, which may lead to suicidal ideation and attempt, so the indication for taking pregabalin in these patients may also be a confounding factor.[2]

In the United States, pregabalin is also indicated as adjunctive therapy in adults with partial onset seizures.[3] It is not approved for this indication in Canada. In December 2008 and April 2009, the US Food and Drug Administration communicated safety notices concerning the increased risk of suicidal behaviour and ideation in patients taking antiepileptic drugs, including pregabalin, for any indication.[4,5]

Health care professionals, patients and caregivers should be aware of

Table 1: Summary of 12 reports of suicidal ideation suspected of being associated with the use of pregabalin submitted to Health Canada as of Dec. 15, 2009*

Case	Patient age/sex	Dose	Indication	Onset of reaction†	Concomitant health products and additional information	Dechallenge‡	Rechallenge§
1	NA/F	25 mg/d	Chronic pain	< 1 day	Zopiclone, hydromorphone	Unknown	Unknown
2	54/F	5 months at 25 mg/d, then increased to 75 mg/d	Pain control	1 day after dose increase	Oxycodone/acetaminophen, clonazepam History of fibromyalgia and back pain	Not applicable (pregabalin therapy ongoing)	Not applicable
3	46/M	150 mg twice daily	Pain	8 days	Citalopram, amitriptyline, lorazepam, clonazepam, fentanyl transdermal patch, morphine, diazepam Post-traumatic stress disorder, marital problems, anxiety, depression, hypomania	Positive	Unknown
4	52/F	75 mg twice daily	Fibromyalgia	About 24 days	Alprazolam, temazepam, topiramate, clonazepam, fluoxetine, oxycodone/acetaminophen, zopiclone, cetirizine, loperamide, ibuprofen, pentosan History of depression and anxiety	Positive	Unknown
5	76/F	25 mg twice daily	Fibromyalgia	2 days	Risedronate, calcium, vitamin D, vitamins, omega-3, glucosamine History of major depression, suicidal thoughts or attempts	Positive	Unknown
6	48/F	25 mg/d	Mood stabilizer	2 days	Mirtazapine History of depression and suicidal ideation	Positive	Unknown
7	24/F	50 mg/d	Affective disorder, mood, sleep	2.5 months	History of depression and suicidal ideation	Not applicable (pregabalin therapy ongoing)	Unknown
8	54/F	25 mg/d	Fibromyalgia	18 days	Clonazepam, dimenhydrinate, acetaminophen/codeine/caffeine, hyoscine, trimebutine, naratriptan, esomeprazole, cetirizine, meloxicam History of bipolar depression and 2 suicide attempts	Positive	Unknown
9	78/M	25 mg three times daily	Chronic pain	2 days	No history of depression or other disorders	Positive	Positive
10	43/F	150 mg twice daily	Fibromyalgia	55 days	Tramadol No history of suicidal thoughts	Positive	Unknown
11	48/F	100 mg twice daily	Pain	NA	Itraconazole, hydrocortisone, doxycycline Ehlers–Danlos syndrome	Unknown	Unknown
12	59/F	Not reported	Neuropathy	NA	None	Not applicable (pregabalin therapy ongoing)	Not applicable

Note: NA = not available.
***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 treatment.
‡Response to withdrawal of the drug. Abatement of reaction after the drug is stopped or the dose is reduced is considered a positive dechallenge.
§Response to reintroduction of the drug. Reappearance of the AR after reintroduction of the drug is considered a positive rechallenge.

adverse reactions suspected of being associated with pregabalin. Health Canada will continue to monitor adverse reactions and will communicate any new safety information or action resulting from its analysis.

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Adverse incidents with injectable hyaluronic acid dermal fillers

Key points

- Health Canada received 32 reports of adverse incidents suspected of being associated with the use of temporary hyaluronic acid dermal fillers.
- The reports included adverse incidents such as pain, edema, nodules, abscesses, as well as one case of lip necrosis and another of partial loss of vision.
- Health care professionals and patients should be aware of these types of adverse incidents.

Many types of dermal fillers are currently marketed in Canada. The types of materials in these injectable products vary from temporary (absorbable) to permanent (nonabsorbable) and from biologic to synthetic compounds.[1,2] Each type of dermal filler has its own specific properties and longevity, as well as advantages and disadvantages.[3] Some dermal fillers contain lidocaine to reduce pain during injection.[1]

Hyaluronic acid (HA) is a temporary dermal filler.[2] It is produced naturally by the body and is a major component of the extracellular matrix of the dermis.[2,4] HA contributes to tissue hydrodynamics by creating space for the movement of cells.[4] It binds with water to fill out the skin.[2] HA dermal fillers are generally used for the correction of moderate to severe facial wrinkles and folds by injection into the mid- to deep layers of the dermis.[1, 5–10]

As of Mar. 15, 2010, over 30 temporary dermal fillers containing HA were licensed for sale in Canada. As of that date, Health Canada had received 32 reports of adverse incidents suspected of being associated with those particular HA dermal fillers. HA dermal fillers mentioned in the case reports were Elevess, Juvéderm, Juvéderm Ultra with Lidocaine, Juvéderm Ultra Plus with Lidocaine, Juvéderm Ultra Plus, Perlane, Restylane, Revanesse, Revanesse Ultra and Teosyal. The reports included adverse incidents such as pain, swelling or edema, nodules, abscesses, presence of pus or infection, skin discoloration or hyperpigmentation, lip necrosis, difficulty talking, swallowing or breathing, and partial loss of vision. The patients were 30 to 75 years old (median 50 years). Fifteen patients were reported to have had the injection of HA dermal filler for the first time. In 7 of the 32 cases, botulinum toxin type A for cosmetic use was also reported to have been used.

Most patients required treatments ranging from abscess drainage to administration of local or systemic drugs such as corticosteroids, antibiotics, antihistamines and anti-inflammatory drugs. In addition, several patients received a local injection of hyaluronidase in order to resolve nodular lesions. Eight patients recovered, and 19 were recovering or had not recovered at the time of reporting (outcome was not reported for 5 patients). Some of the adverse incidents persisted for weeks or months after the injection.

One patient who had received an injection of HA dermal filler (Restylane) into the lips reported gangrene and necrosis of the lips. Another patient experienced partial loss of vision after injection of Juvéderm Ultra with Lidocaine to the tear trough (lower eyelid), Juvéderm Ultra Plus with Lidocaine to the cheek and Juvéderm Ultra Plus to marionette lines (lines that extend from the outer corner of the mouth towards the chin). Botulinum toxin type A was injected into the chin and smoker's lines (vertical wrinkles above the upper lips) on the same day. A follow-up scan was normal, with no dermal filler detected intra-orbitally; no injury to the optic nerve was observed. The patient had not recovered at the time of reporting. A case of partial loss of vision was previously published.[11]

Adverse incidents such as pain, swelling or edema, nodules, induration, abscesses, granuloma and skin discoloration are generally labelled in the instructions for use for various HA dermal fillers.[5–10] These instructions contain warnings or contraindications with regard to injection into blood vessels. The glabella, the area between the eyebrows, is the injection site commonly believed to be at increased risk of skin necrosis.[12] This can be attributed to an interruption of vascular supply owing to compression or obstruction of blood vessels by direct injection into a vessel.[12]

HA dermal fillers are the most popular temporary fillers, and their use is growing.[4,13,14] They are considered to provide an effective, noninvasive and nonsurgical alternative for the correction of soft-tissue defects of the face.[13] The health care professional who injects dermal fillers must have proper training in their use and be aware of the types of adverse incidents that can occur, as well as contraindications.[12]

Health Canada encourages the reporting of adverse incidents suspected of being associated with the use of HA dermal fillers, or any other

medical devices, to the Health Products and Food Branch Inspectorate through the toll-free hotline (1-800-267-9675).

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Oral iron supplements: skin reactions and other hypersensitivity reactions

Key points

- In Canada, oral iron supplements are regulated as natural health products.
- Health Canada received reports of skin and other hypersensitivity reactions suspected of being associated with the use of oral iron supplements.
- Some adverse reactions may be serious and may involve multiple systems.

Oral iron supplements are used to prevent or treat iron deficiency.[1] Iron deficiency is a common cause of anemia and can result from inadequate iron intake, malabsorption, blood loss or increased requirement (e.g., pregnancy).[2] Several different oral iron supplements exist, and depending on the source, their content of elemental iron may vary. The content of elemental iron in commonly used preparations is 11.6% for ferrous gluconate, 20% for ferrous sulfate and 33% for ferrous fumarate.[1]

In Canada, oral iron supplements are regulated as natural health products.[3] Health Canada has adopted the US Institute of Medicine's recommendations on the tolerable upper intake level for total elemental iron intake from food and supplements: 40 mg/d for children aged 0–13 years and 45 mg/d for people 14 and older.[4] The upper intake level is the maximum daily oral intake unlikely to result in adverse health effects in the general population. Higher doses may be recommended by health care professionals for the treatment of iron deficiency or iron deficiency anemia.

From Jan. 1, 1965, to Dec. 31, 2009, Health Canada received 108 reports of skin and other hypersensitivity reactions suspected of being associated with the use of oral iron supplements. The reactions included cutaneous and subcutaneous reactions (e.g., rash, pruritus, urticaria, hives, erythema, edema, photosensitivity), as well as some reactions involving multiple systems (e.g., cardiovascular, respiratory, gastrointestinal) with or without skin reactions, including anaphylaxis. Of these reports, 24 were considered serious;* 8 of them were associated with a single-ingredient iron supplement without exposure to other suspected health products (Table 1). Some patients were using concomitant health products but none of these products was suspected of being associated with the adverse reactions (ARs).

Of the remaining 16 reports of serious ARs, one report described a

*In the *Natural Health Products Regulations*, a serious adverse reaction means "a noxious and unintended response to a natural health product that occurs at any dose and that requires in-patient hospitalization or a prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life-threatening or that results in death."

Table 1: Summary of 8 serious reports of hypersensitivity reactions suspected of being associated with the use of single-ingredient oral iron products, without exposure to other suspected health products, submitted to Health Canada as of Dec. 31, 2009*

Case	Patient age/sex	Oral iron product	Daily dose, mg†	Adverse reaction‡
1	NA/F§	Fesofor¶ (ferrous sulfate)	65	Severe rash all over body
2	33/M	Apo-Ferrous sulfate	120	Urticaria (hives around neck up to ears), dyspnea
3	64/M	Novo-Ferrosulfa¶ (ferrous sulfate)	180	Heart rate increased, hyperhidrosis, discoloration, exfoliation and swelling of lips, respiratory rate increased, tongue discoloration, tongue exfoliation
4	66/M	Ferrous sulfate	120	Pustular rash on face, dysphonia, gastroesophageal reflux disease
5	77/F	Apo-Ferrous gluconate	70	Dysphagia, hypertension, swollen tongue, vomiting
6	32/F	Ferrous gluconate	35	Asthenia, chest discomfort, dizziness, dyspnea, oral hypoesthesia, tremor
7	15/F	Palafer (ferrous fumarate)	100	Anaphylactic reaction, cough, dyspnea, dysphonia, swollen and itchy eyes, hyperhidrosis, hypotension, rash, sneezing, urticaria
8	39/F	Proferrin (heme iron polypeptide)	22	Angioedema, dyspnea, peripheral edema, face swelling

Note: NA = not available.
***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 health product was on the market has been taken into consideration.**
†Daily dose based on the amount of elemental iron.
‡Reaction terms are listed according to the *Medical Dictionary for Regulatory Activities* (MedDRA).
§Patient was pregnant.
¶Product no longer marketed in Canada.

patient with Stevens–Johnson syndrome suspected of being associated with the use of 4 different health products, including ferrous gluconate, acetylsalicylic acid, prednisone and ketorolac. One fatal case was reported that involved circulatory and respiratory collapse suspected of being associated with the use of health products including ferrous gluconate, chlorpromazine and furosemide. In this case, the patient had hemolytic anemia, a contraindicated health condition for the use of oral iron salts.[1]

Cases of serious cutaneous and anaphylactic reactions (e.g., pustular drug eruption, photosensitization, generalized pruritus, pruriginous papules, urticaria, shortness of breath, hypotension) associated with single-ingredient iron products have been published previously.[5–8] Also, the Netherlands Pharmacovigilance Centre has received reports of cutaneous reactions (e.g., rash, urticaria, erythema, photosensitivity, hyperpigmentation) associated with the use of oral iron salts.[9]

Other contributing factors may be involved in reactions to oral iron-containing products, including hypersensitivity to an excipient in the product such as a colorant (e.g., azo-dye Sunset Yellow).[10] In addition, several reports stated that the patients used other health products, or were using a multiple-ingredient product containing iron (e.g., multivitamin), which makes it difficult to assess the association with iron.

Health care professionals are reminded of potential adverse hypersensitivity reactions associated with the use of oral iron supplements. Although typically not serious, some reactions may be serious and may involve multiple systems. Patients who experience skin reactions or other types of hypersensitivity reactions with the use of oral iron supplements should consult their health care professional. Health care professionals and patients are encouraged to report ARs suspected of being associated with natural health products to Health Canada.

Stephanie Jack, MSc; Hélène Lacourcière, MD; Danika Painter, PhD; Mimi Hum, RN, BNSc, Health Canada

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Quarterly summary of health professional and consumer advisories

(posted on Health Canada's Web site: Feb. 20, 2010 – May 21, 2010)

Date*	Product	Subject
May 17	Foreign products	Alerts – Botanical Slimming 100% Natural Soft Gel (Meizitang); Marsha Slim Plus; S&S Super Slender
May 12 & 17	Maalox Multi Action	Confusion with other Maalox liquid products
May 12	Tysabri	Association with multifocal leukoencephalopathy
May 12	Miracle Mineral Solution	Unauthorized health product
May 7	Rotavirus Vaccines	Presence of porcine circovirus DNA
May 4	Children & Infant's Motrin & Tylenol	Update – recall concerning manufacturing issues
May 3	Foreign products	Alerts – Ba Bao Xiao Ke Dan; Bao Shu Tang Wu Zi Yan Zong Wan; Lin Yan Yin Chiao; Man Power; 17 products sold through MuscleMaster.com; Seven Slim 7 Seshou (Qingchun Shaonüxing), (Jieshixing), (Guifurenxing), (Songchixing), Shoushen Jiaoguan-Tinei Yundong Wan (Jian Xiabanshen), (Jian Quanshen Feipang)
Apr 30 & May 5	Exelon Patch	Serious adverse events related to medication errors/misuse
Apr 28	Slim-30	Unauthorized health product
Apr 26	Promethazine hydrochloride injection	Revised labelling
Apr 15	Cuffed Shiley Tracheostomy Products	Urgent recall for certain lots
Apr 14 & 20	Invirase	Significant dose-dependent prolongations of QT and PR intervals
Apr 9	Adjuvanted H1N1 vaccine (Arepanrix)	New expiry date
Apr 9	Zeftera	Discontinuation of sale
Mar 31	West Pharm Therma Lean Fat Burner Energizer	Unauthorized health product
Mar 25	Herbal Diet Natural	Unauthorized health product
Mar 23	Ratio-Prednisolone eye drops	Recall – some bottles may contain particles
Mar 22	WinRho SDF	Association with intravascular hemolysis in the treatment of immune thrombocytopenic purpura
Mar 22	Avelox	Rare risk of severe liver injury
Mar 18	OneTouch SureStep Test Strips	Possibility of low test results
Mar 12	Medical device clocks	Update – reminder to switch to Daylight Savings Time
Mar 8 & 10	Fentanyl transdermal systems	Changes to dose conversion guidelines
Mar 8	Power-Max	Unauthorized health product
Mar 1	Foreign products	Alerts – Certain lots of sexual enhancement dietary supplements sold by Atlas Operations Inc.; 2H & 2D; 65 products sold through Bodybuilding.com; STRO Emperor Capsules; Tian Yang Xu Huo Oral Ulcer Capsule
Feb 19	OM Fusion health products	Unauthorized health products
Feb 18	Zinc-containing Poli-Grip	Association with myeloneuropathy and blood dyscrasias

Advisories are available at www.healthcanada.gc.ca/medeffect.
*Date of issuance. This date may differ from the posting date on Health Canada's Web site.

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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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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.