

Labelling of Iron Products

Healthcare professionals have alerted ISMP Canada to the incorrect labelling of one iron product (Figure 1) and the potential for misinterpretation of another product label (Figure 2). Although to date there have been no reports of over-ingestion with either of these products, there is a potential for harm from over-ingestion of iron, and ISMP Canada has therefore alerted Health Canada and the manufacturers of these products about the labelling concerns.

The bottles illustrated in Figures 1 and 2 both contain tablets of ferrous gluconate 300 mg, providing elemental iron 35 mg. The product labels could be interpreted to mean that each tablet contains only 35 mg of ferrous gluconate, which could in turn lead to ingestion of much greater amounts of iron than intended. For example, a patient who has been instructed to take 300 mg of ferrous gluconate may incorrectly conclude that multiple tablets are needed to fulfill the dose requirement.¹ This potential for confusion exists even if the side panel of the label provides more detailed information, since the fine print on the side panel may be overlooked.

In the past, the front panel of the label on iron products available in pharmacies typically expressed the strength as, milligrams of the iron salt (e.g., ferrous gluconate 300 mg),

with the elemental iron content often provided only on the side panel. More recently, there has been a move to include the elemental iron content on the front panel. Ideally, both the elemental iron content and the total amount of the iron salt should be prominently displayed on the main label, for example, *each tablet of Ferrous Gluconate 300mg contains Iron 35 mg.*

Under current regulations, Canadian pharmacies must keep iron products containing more than 30 mg of elemental iron per solid dosage unit in an area where there is “no opportunity for self-selection”² by the consumer (i.e., behind the counter). This restriction affords opportunities for pharmacists to review with the consumer relevant information related to the purchase of an iron product and to provide counselling. However, it does not eliminate the need for standardized labelling of the main product panel. If natural health products are removed from the National Drug Schedules on Jan 1, 2010, as currently planned,³ pharmacies will no longer be required to keep products with higher elemental iron content behind the counter. As such, these products will become more widely available in nonpharmacy outlets such as health food stores, which will increase the importance of clear labelling for consumer use.



Figure 1. Novopharm ferrous gluconate product label introduced in mid-December 2008. This label is *incorrect*. The label indicates that each tablet contains ferrous gluconate 35 mg; however, each tablet actually contains ferrous gluconate 300 mg providing 35 mg of elemental iron.

A Novopharm spokesperson has informed ISMP Canada that the company has voluntarily stopped shipment of this product and is changing the main panel of the label for future shipments.

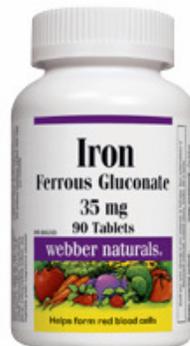


Figure 2. This Webber Naturals product contains elemental iron 35 mg. The layout of the information on the label could lead the user to think that each tablet contains ferrous gluconate 35 mg.

Although a spokesperson for WN Pharmaceuticals has indicated that the company is no longer producing iron products, this example is provided to illustrate the need for a standardized approach to the labelling of iron products.

Please report any concerns related to the labelling of iron products to Health Canada's Health Products and Food Branch Inspectorate at: 1-800-267-9675

You may also contact ISMP Canada at 1-866-544-7672 or report your concern online at:
https://www.ismp-canada.org/err_report.htm

Acknowledgements

ISMP Canada gratefully acknowledges the input provided by James E. G. Snowdon, RPh, BScPhm, PharmD, FACA; and the expert review of this bulletin by (in alphabetical order) Patti Cornish, RPh, BScPhm, Patient Safety Service, Sunnybrook Health Sciences Centre; Ian Stewart, RPh, BScPhm, Community Pharmacist; and John W. Senders, PhD, Professor Emeritus, University of Toronto.

References

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Community Pharmacy Medication Safety Assessment Program

The Medication Safety Self-Assessment® (MSSA) for Community/Ambulatory Pharmacy was developed to guide individual community pharmacies in identifying opportunities for medication safety enhancements. The self-assessment criteria in the program are related to potential system improvements that have been identified through analysis of medication incidents. Our collective challenge is to translate that knowledge into practice, and the MSSA for Community/Ambulatory Pharmacy is one way to do so.

Several provinces in Canada are supporting use of this program as a component of quality improvement initiatives. The program's web-based interface allows an individual pharmacy to compare its results with the aggregate results of other respondents, both regionally and nationally, and also encourages evaluation of improvement efforts over time.

For more information about the MSSA program for community pharmacy practice, please contact us by email: mssa@ismp-canada.org or by telephone: 1-866-544-7672.

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

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

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

ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. 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.

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