Institute for Safe Medication Practices Canada
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A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

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Confusing Calcium Product Labels Lead to Hospitalizations

- ***Manufacturers:*** Standardize the labelling of calcium and other similar products to accurately display the strength in terms of both the elemental and the salt content on the principal display panel.
- ***Pharmacists:*** Inform patients about the difference between elemental calcium and calcium salts, and ensure that every patient understands their dose.
- ***Prescribers:*** Provide clear written instructions for the patient; these should include the elemental calcium content, the preferred salt (if any), the dose, and the frequency of use.

Calcium supplements are available for purchase without a prescription but may also be prescribed or recommended by health care providers for patients with confirmed or suspected calcium deficiency, or as a phosphate binder. Currently, calcium product labels may display the strength of the supplement in terms of either elemental calcium or the calcium salt, or both. ISMP Canada has received reports describing incidents associated with confusion about the labelled strength. In some cases, unintentional overdoses have resulted in patients being admitted to the intensive care unit. This bulletin shares incident examples to raise awareness of the risks associated with the lack of standardization of calcium product labels, as well as to highlight opportunities to improve labelling practices.

INCIDENT EXAMPLES

In 3 separate incidents, calcium carbonate 1250 mg (a calcium salt providing elemental calcium 500 mg) was prescribed for a patient discharged from hospital post-parathyroidectomy or thyroidectomy. In each case, the patient purchased a product labelled as calcium carbonate 500 mg (see Figure 1 for an example of this type of labelling). Each patient took 2.5 tablets per dose, not realizing that the 500 mg presented on the primary display panel (i.e., main or front panel) label reflected the tablet strength in terms of elemental calcium (such that 1 tablet would be sufficient for the prescribed dose). All 3 patients required admission to the intensive care unit for treatment to correct hypercalcemia resulting from the overdose.

In a fourth reported incident, a pharmacy dispensing error occurred when a patient's blister pack was prepared. The prescription for calcium carbonate 1250 mg 3 times daily was supplied as 2.5 tablets for each dose, based on the front panel label indicating the tablet strength as calcium carbonate 500 mg. Although no harm came to this patient, additional blood work was required.

Figure 1:

Front panel label incorrectly displaying calcium salt with elemental calcium strength.

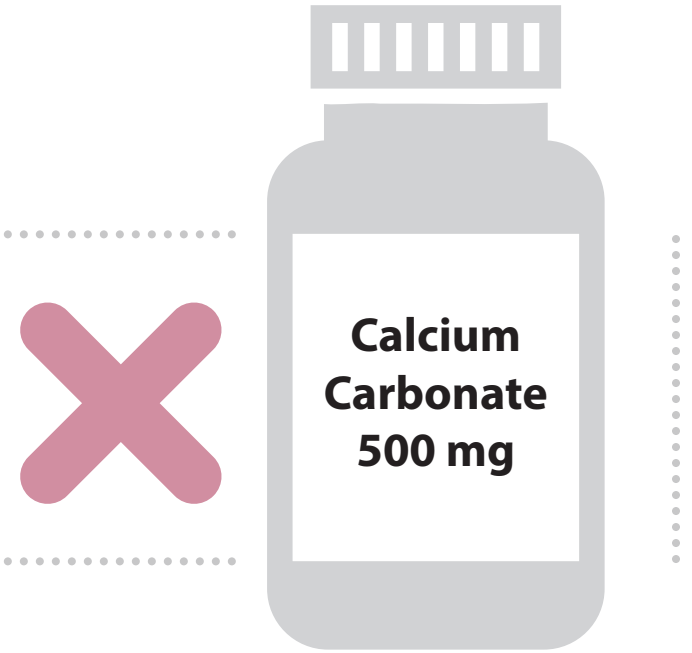
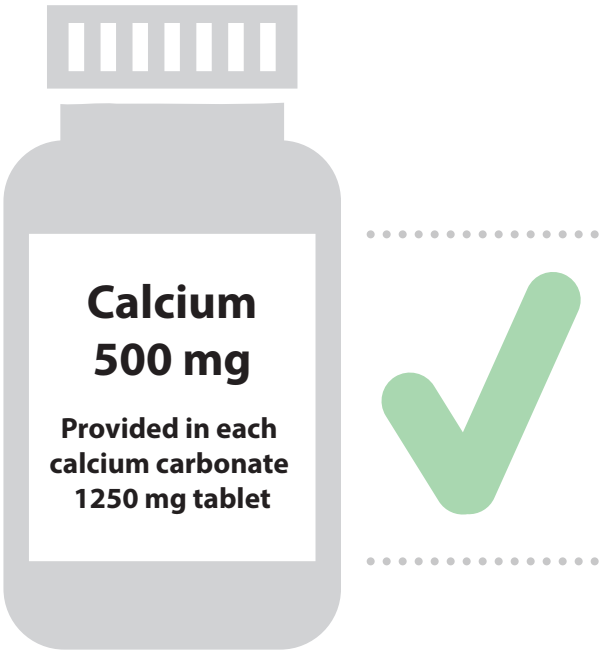


Figure 2:

Front panel label correctly displaying both the elemental calcium and calcium salt strength.

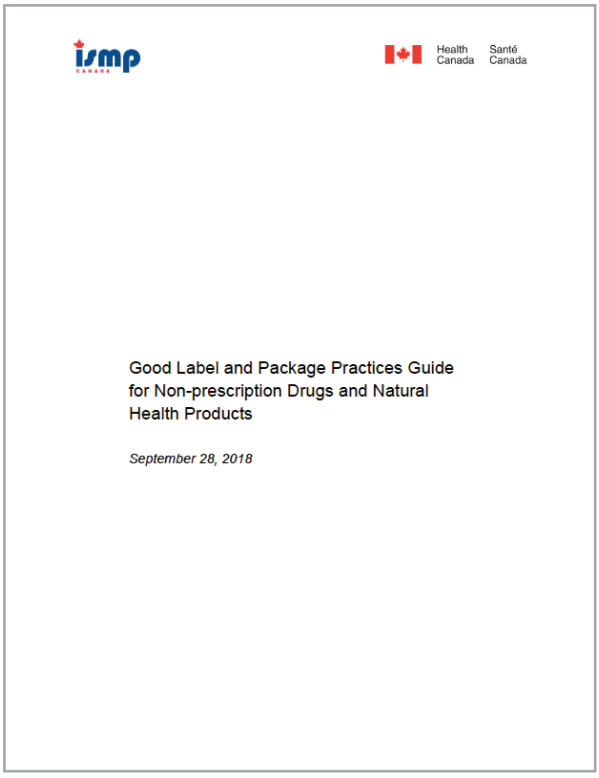


BACKGROUND

Calcium is an essential mineral element involved in bone metabolism, as well as other physiological electrochemical processes. A typical dose of calcium prescribed or recommended is 500-1000 mg of elemental calcium to obtain the recommended daily dietary allowance of 1000-1200 mg (elemental calcium) for most adults.[1] Supplements are available only as compounds (i.e., as calcium salts), with calcium carbonate and calcium citrate being the 2 most common forms. During digestion, the body breaks down the calcium salt and only absorbs the elemental calcium.[2] Calcium carbonate contains 40% elemental calcium (i.e., a 1250 mg tablet of calcium carbonate provides 500 mg of elemental calcium), whereas calcium citrate contains approximately 20% elemental calcium (i.e., a 1250 mg tablet of calcium citrate provides 250 mg of elemental calcium).[2]

Currently, calcium products do not display the tablet strength in a consistent format on the front panel in terms of either the elemental calcium or the calcium salt content. Adding to this variability is the fact that some products are labelled as the calcium salt, but the displayed strength reflects the elemental calcium content. ISMP Canada has identified several calcium products that have been incorrectly labelled (as illustrated in Figure 1). Misinterpretation of the product label because of inadequate or confusing labelling practices is problematic and can lead to over- or under-dosing and harmful outcomes.[3] Since some natural health products, including calcium supplements, are available for self-selection and can be purchased without a prescription from a variety of retail or online outlets, patients may not always have access to the assistance of a pharmacist when choosing a product.

Although similar concerns have been raised about labels for iron supplements,[4] most iron products must be kept behind the pharmacy counter and are not available for self-selection. Federal regulations require non-prescription products with a DIN to have a Drug Facts Table on the outer package by June 2021, and a similar requirement for products with a Natural Product Number (NPN), including mineral supplements, is under consideration. A Facts Table or equivalent for a mineral compound like calcium, should contain information pertaining to both the salt and the elemental components of the product. In 2016 Health Canada and ISMP Canada published the "Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products" to assist manufacturers in developing safe product labels; it includes a recommendation that for mineral supplements, both the strength of the elemental content and that of the salt be presented on the front panel label.[5]



DISCUSSION

Analysis of the incidents with calcium carbonate indicated that the key contributing factor was confusing information on the front panel of the label.

On the basis of the incorrect front panel label (i.e., "calcium carbonate 500 mg"), the patients and pharmacy staff in the incidents described above determined that 2.5 tablets were required for each prescribed dose of calcium carbonate 1250 mg. The prescribed doses were appropriate and were correctly understood to mean calcium carbonate 1250 mg 1 to 3 times daily (equivalent to elemental calcium 500 mg 1 to 3 times daily). The patients and health care providers relied on the information on the front panel label to determine the number of tablets required to obtain the prescribed dose.

RECOMMENDATIONS

There is a need for all stakeholders – prescribers, pharmacy professionals, manufacturers, and regulatory agencies – to join together to ensure practices are improved.

Manufacturers of Calcium and Other Mineral Supplements

- Follow the recommendation in the "Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products" related to the expression of strength for mineral salts. Standardize labelling to accurately display the strength of minerals such as calcium in terms of both the elemental and salt content. This will promote consistency in label format and nomenclature which is essential to reduce the risk of medication dosing errors.
  - **The front panel label should clearly state the strength of both forms**, for example: "elemental calcium 500 mg (provided in each calcium carbonate 1250 mg tablet)".[5]
  - Including a Product Facts Table can add clarity at the point of product selection and reduce the potential for misinterpretation of the product strength.

Community Pharmacists

- When possible, stock only those brands of calcium products that provide a clear and accurate description of the calcium content on the front panel label.
- Provide signage, in the area where calcium products are stocked, advising patients to check with the pharmacist for help selecting a product and confirming the dose.
- When patients ask about calcium products:
  - inform them that the dose of elemental calcium is not the same as the dose of a calcium salt.
  - ensure that they understand what their dose is (i.e., in terms of the number of tablets per dose).
  - emphasize the need to specify whether their calcium dose is being expressed as elemental or as the salt when they communicate with other health care providers.
- Clarify the dose with the prescriber if it is unclear whether a prescription is expressed in terms of elemental calcium or calcium salt (and if so, which calcium salt).
- Ask prescription software vendors to include the elemental calcium content as part of the information displayed for calcium salts on product selection screens.

Prescribers

- Before prescribing or recommending a product, advise patients about the different forms of calcium available.
- Provide clear written instructions for the patient; these should include the elemental calcium content, the preferred salt (if any), the dose, and the frequency of use.
- Suggest that the patient speak to their pharmacist for assistance when selecting a calcium product and calculating the number of tablets that will correctly provide the recommended dose.
- Request vendors of electronic medical records to ensure the on-screen display of calcium products include the elemental calcium and calcium salt content.

CONCLUSION

This bulletin highlights the importance of clear, accurate labels for natural health products. In particular, consistent and accurate labelling of mineral supplements such as calcium is essential to reduce confusion for both patients and health care providers. The labelling on the front panel of the product should prominently display critical information; for calcium products, this includes showing the product strength in terms of both elemental calcium and the calcium salt. ISMP Canada will be following up with manufacturers of calcium products with incorrect labels.

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SafeMedicationUse.ca

Antibiotic Suspension Lacking a Child-Resistant Closure Contributes to Overdose

ISMP Canada's consumer reporting program, SafeMedicationUse.ca, received a report describing a young child who drank amoxicillin suspension directly from a bottle holding the antibiotic. The bottle had been provided to a child-care centre for administration of daytime doses by staff. The child came into possession of the bottle at the centre and thought it was a drink. The child's parent was alerted to the overdose and called a poison centre for guidance.

The parent reported that the bottle did not have any type of child-resistant closure. ISMP Canada contacted the manufacturer of the product, Apotex, who confirmed that the company's amoxicillin suspension is being manufactured by a third party and the packaging does not include a child-resistant closure. Apotex is now working with the supplier to ensure that the packaging incorporates a child-resistant closure. Health Canada has also been made aware of the situation and will follow up with the company. This information is being shared to alert community pharmacy practitioners to the current packaging, so that parents and other caregivers can be informed of the potential safety risks, as well as the planned packaging change.

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