

ISMP Canada Safety Bulletin

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ALERT: Risk of Dose Errors with Transition to New Formulation of Rybelsus

A new formulation of Rybelsus* (referred to as an optimized formulation in the product monograph and throughout this alert) is now available in Canada.^{1,2} During the transition period (i.e., until remaining stock of the initial formulation is depleted), both formulations may be available in pharmacy, hospital, and/or wholesaler inventories, and references to both may appear in pharmacy or prescriber electronic information systems, potentially increasing the risk for dose equivalency errors.

BACKGROUND

The optimized formulation is bioequivalent to the initial formulation, but not on a milligram per milligram basis.²⁻⁴ It was formulated with modified excipients to increase absorption (thereby increasing bioavailability); as a result, lower doses of semaglutide (in milligrams [mg]) are needed to achieve the same therapeutic effect.^{1,3,4} Figure 1 displays the dose equivalencies between the initial and optimized formulations.

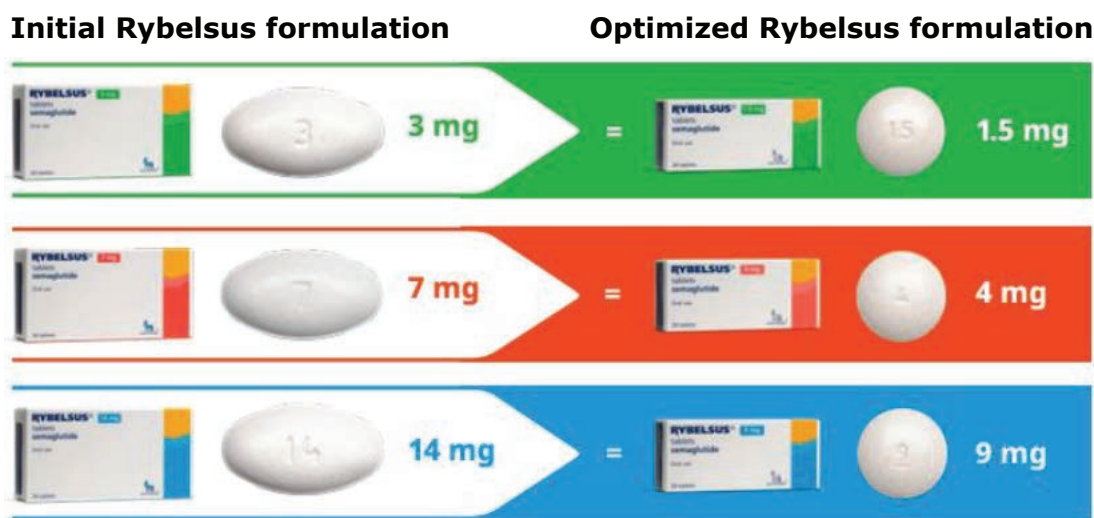


FIGURE 1. Infographic of initial and optimized formulations of Rybelsus tablets, courtesy of Novo Nordisk Canada. *Note: The optimized formulation tablets have a different shape (round instead of oval-shaped) and size (smaller) than the initial formulation.*

* Rybelsus is the brand name for an oral formulation of semaglutide, used by adults with type 2 diabetes.¹

INCIDENT EXAMPLES

- A refill request for Rybelsus 7 mg (initial formulation) was dispensed with a mix of 3 mg (initial formulation) and 4 mg (optimized formulation) tablets; this was equivalent to 10 mg of the initial formulation. This incident was discovered during prescription pick-up.
- A prescription for Rybelsus 9 mg (optimized formulation) was dispensed as 3 mg (initial formulation) tablets with directions to take 3 tablets daily; this was equivalent to 4.5 mg of the optimized formulation. This incident was recognized during a medication review.

DISCUSSION

Canadian pharmacists have reported concerns about the lack of awareness of the optimized formulation, the difficulty in differentiating the initial and optimized formulations in electronic systems (Figure 2), the need to convert doses when using the optimized formulation (Figure 1), and the availability of both formulations on pharmacy shelves.

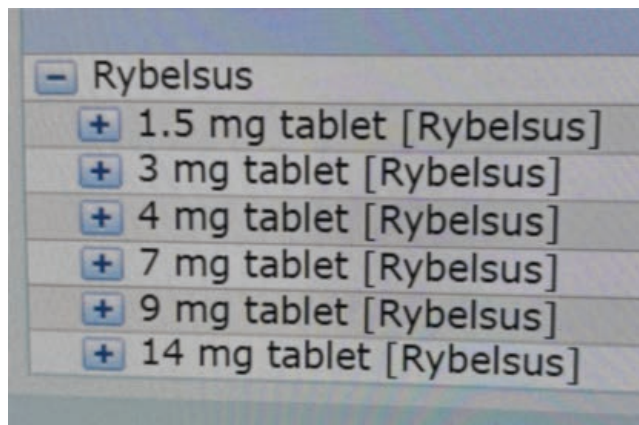


FIGURE 2. Screenshot of Rybelsus selection options from an electronic system. Note the lack of differentiation between initial and optimized formulations of Rybelsus.

RECOMMENDATIONS

Given that both formulations may still be available in electronic systems and wholesaler inventories, and on pharmacy shelves, the following actions can help prevent dose equivalency errors.

Electronic Systems

- Distinguish the initial and optimized formulations of Rybelsus in electronic systems, including patient records, prescribing modules, pharmacy systems, and medication administration records.
- Create a pop-up in electronic systems to alert users to the optimized formulation of Rybelsus and provide dose equivalency information (Figure 1).
- Once stock of the initial formulation has been depleted, deactivate the corresponding drug files in electronic systems.

Pharmacy Processes

- Communicate within the circle of care about the optimized formulation. Pharmacists can switch patients to the equivalent optimized formulation, document the change, and inform the prescriber.⁵
- Place a warning about dose equivalencies on the shelf where Rybelsus products are stored.

Patient/Caregiver Engagement

- Inform patients/caregivers about the change in tablet strength, shape, and size (i.e., lower, round, and smaller). Emphasize that Rybelsus is always to be taken as a single tablet once daily and tablets should not be combined to make up a dose.^{1,5} Describe the potential risk of harm if the different formulations are inadvertently mixed up or combined.
- Help patients/caregivers to update their own medication lists to reflect the change in strength of Rybelsus.

ACKNOWLEDGEMENTS

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CMIRPS SCDPIM

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