

FDA Required REMS Safety Information

- Risk of severe hypoglycemia with use of SYMLIN added to mealtime insulin
- Importance of insulin dose reduction
- Proper patient selection

Important Safety Update

The FDA has required this safety update as part of the SYMLIN REMS (Risk Evaluation and Mitigation Strategy) program to inform health care providers about the following **serious risks of SYMLIN (pramlintide acetate)**:

- **Increased risk of severe hypoglycemia, particularly in patients with type 1 diabetes.**
- **Importance of insulin dose reduction**
Counsel and instruct your patients on insulin dose reduction to minimize the risk of hypoglycemia.
- **Proper patient selection.** SYMLIN is **contraindicated** in patients with any of the following:
 - Hypoglycemia unawareness
 - Confirmed gastroparesis
 - Serious hypersensitivity to SYMLIN or any of its product components

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information is enclosed.

Indication: SYMLIN is an amylin analog indicated for patients with type 1 or type 2 diabetes who use mealtime insulin and have failed to achieve desired glycemic control despite optimal insulin therapy.

Please visit www.SYMLINREMS.com for more information.

This letter does not contain the complete safety profile for SYMLIN. Please see the Prescribing Information and Medication Guide, enclosed.

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Sincerely,



James Blasetto MD, MPH
VP US Medical Affairs, Evidence Generation

Enclosure: REMS Factsheet, SYMLIN Prescribing Information with Medication Guide



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