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) to inform healthcare 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
- 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 available. Please visit www.SymlinREMS.com for more information.

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.

This letter does not contain the complete safety profile for SYMLIN.

To review the Prescribing Information and Medication Guide, see links below:

Prescribing Information | Medication Guide

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.

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