FDA Required SYMLIN REMS Safety Information

WARNING: SEVERE HYPOGLYCEMIA

SYMLIN use with insulin increases the risk of severe hypoglycemia, particularly in patients with type 1 diabetes. When severe hypoglycemia occurs, it is seen within 3 hours following a SYMLIN injection. Serious injuries may occur if severe hypoglycemia occurs while operating a motor vehicle, heavy machinery, or while engaging in other high-risk activities. Appropriate patient selection, careful patient instruction, and insulin dose reduction are critical elements for reducing this risk.

Proper Patient Selection

SYMLIN is contraindicated in patients with any of the following:

- serious hypersensitivity reaction to SYMLIN or to any of its ingredients;
- hypoglycemia unawareness;
- confirmed gastroparesis.

Proper patient selection is critical to the safe and effective use of SYMLIN. Before initiating SYMLIN, the patient's HbA1c, recent blood glucose monitoring data, history of insulin-induced hypoglycemia, current insulin regimen, and body weight should be reviewed. SYMLIN therapy should only be considered in patients with type 1 diabetes or patients with type 2 diabetes using mealtime insulin who fulfill the following criteria:

- have failed to achieve adequate glycemic control despite individualized insulin management;
- are receiving ongoing care under the guidance of a healthcare professional skilled in the use of insulin and supported by the services of diabetes educator(s)

Patients meeting any of the following criteria should **NOT** be considered for SYMLIN therapy:

- poor compliance with current insulin regimen;
- poor compliance with prescribed self blood glucose monitoring;
- have a HbA1c >9%;
- recurrent severe hypoglycemia requiring assistance during the past 6 months;
- presence of hypoglycemia unawareness;
- confirmed diagnosis of gastroparesis;
- require the use of drugs that stimulate gastrointestinal motility;
- pediatric patients;
- SYMLIN should be prescribed with caution to persons with visual or dexterity impairment.

Insulin Dose Adjustment

When initiating SYMLIN, **reduce mealtime insulin doses, including premixed insulins, by 50% to reduce the risk of hypoglycemia (see DOSAGE and ADMINISTRATION of the SYMLIN prescribing information).**

Monitor blood glucose frequently, including pre- and post-meals and at bedtime, particularly when initiating SYMLIN or increasing the SYMLIN dose.

After the initial 50% reduction in mealtime insulin dose, individualize insulin dose adjustments based on glycemic control and tolerability (e.g., if nausea occurs it may affect the dose of insulin required).

An increased frequency of mild to moderate hypoglycemia should be viewed as a warning sign of increased risk for severe hypoglycemia.

SYMLIN alone does not cause hypoglycemia. However, SYMLIN is indicated to be co-administered with mealtime insulin therapy and in this setting there is an increased risk of severe hypoglycemia, particularly in patients with type 1 diabetes.

The addition of any anti-diabetic medication such as SYMLIN to an existing regimen of one or more anti-diabetic medications (e.g., sulfonylurea), or other medications that can increase the risk of hypoglycemia may necessitate further insulin dose adjustments and particularly close monitoring of blood glucose.

SYMLIN dosage differs depending on whether the patient has type 1 or type 2 diabetes. Please read the recommendations in the SYMLIN Prescribing Information on proper DOSAGE and ADMINISTRATION.

SymlinPen®
(pramlintide acetate)
pen-injector

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A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks. The FDA has required a REMS for SYMLIN.

The purpose of this non-promotional Factsheet is to mitigate the risk of severe hypoglycemia associated with SYMLIN by:

- informing health care providers about the risk of severe hypoglycemia as SYMLIN is used with insulin and the importance of insulin dose reduction
- informing health care providers of the importance of proper patient selection for treatment with SYMLIN

Reporting Adverse Events

To report all suspected adverse events associated with the use of SYMLIN, please contact:

1-800-721-5072

FDA Medwatch Program at 1-800-FDA-1088 or www.fda.gov/medwatch

For more information regarding SYMLIN, please contact the Medical Information department at 1-800-321-1335 or visit the website at www.SYMLIN.com.

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