SymlinPen® (pramlintide acetate) pen-injector

INDICATION

SYMLIN® (pramlintide acetate) injection is indicated as an adjunctive treatment in adults with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

IMPORTANT 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.

Please click here for US Full Prescribing Information for SYMLIN, including **Boxed WARNING** regarding severe hypoglycemia.

	Type 1 Diabetes
	Dose Titration Study (SYMLIN Prescribing Information[1])
Study purpose	Evaluate efficacy and safety of pramlintide plus insulin compared to insulin alone
Study design	6-month, double-blind, randomized, placebo-controlled
Key inclusion criteria	Adult patients with type 1 diabetes who had a mean age of 41 years
Patient populations	N = 295, MDD: 20 years, Mean A1C: 8.1%
Dosing	Pramlintide initiated at 15 mcg before major meals with insulin dose reduced by 30% to 50% to minimize hypoglycemia. Pramlintide titrated weekly (15-mcg increments) to a final maintenance dose of 30 mcg or 60 mcg with flexible insulin dosing.
Primary efficacy endpoint	Change in A1C at 6 months
Selected secondary and other endpoints	Change in body weight, change in insulin use

Abbreviation: MDD, mean duration of diabetes

Reference:

1. SYMLIN Prescribing Information.