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.

	Pharmacodynamics
	Dose Timing Study (Weyer et al[1] and Maggs et al[2])
Study purpose	Evaluate PPG concentrations of SYMLIN® (pramlintide acetate) injection as adjunct to insulin lispro or regular insulin following a standardized mixed meal test for 5 consecutive days
Study design	Randomized, single-blind, placebo-controlled, 5-way crossover pharmacodynamic
Key inclusion criteria	Adult patients aged 18-65 with type 1[5] or type 2[6] diabetes for at least 1 year and inadequate glycemic control (A1C ≥ 7.0% and ≤ 11.0%) who were free from symptoms of severe hyper- and hypoglycemia
Patient populations	Type 1 diabetes: n = 21 using insulin lispro, n = 19 using regular insulin Type 2 diabetes: n = 19 using insulin lispro
Dosing	On each day, patients received 1 of 5 treatments relative to the standardized meal (breakfast): Type 1: placebo at -15 minutes (min) or pramlintide 60 mcg at -15 min, 0 min, +15 min, or +30 min. Regular insulin was injected at -30 min and insulin lispro at 0 min Type 2: placebo at -15 min or pramlintide 120 mcg at -15 min, 0 min, +15 min, or +30 min. Insulin lispro was injected at 0 min
Primary efficacy endpoint	Plasma glucose area under the concentration time curve from 0 to 2 hours and 0 to 4 hours
Selected secondary and other endpoints	Incidence of treatment-emergent adverse events

Abbreviation: PPG, postprandial glucose

References:

1. Weyer C, Gottlieb A, Kim DD, et al. Pramlintide reduces postprandial glucose excursions when added to regular insulin or insulin lispro in subjects with type 1 diabetes. *Diabetes Care*. 2003;26(11):3074-3079.
2. Maggs DG, Fineman M, Kornstein J, et al. Pramlintide reduces postprandial glucose excursions when added to insulin lispro in subjects with type 2 diabetes: a dose-timing study. *Diabetes Metab Res Rev*. 2004;20(1):55-60.