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 2 Diabetes	
	Trial 1 (Hollander et al[1])	**Trial 2** (Data on File[2])
Study purpose	Evaluate efficacy and safety of pramlintide plus insulin compared to insulin alone	Evaluate efficacy and safety of pramlintide plus insulin compared to insulin alone
Study design	52-week, phase 3, double-blind, randomized, placebo-controlled, parallel-group, multicenter	26-week, phase 3, double-blind, randomized, placebo-controlled, parallel-group, multicenter
Key inclusion criteria	Adult patients aged ≥18 with type 2 diabetes requiring insulin treatment for at least 6 months and inadequate glycemic control (A1C ≥8.0%) who were free from symptoms of severe hyper- and hypoglycemia for 2 weeks; stable insulin dosing (no more than ±10%) for at least 2 months prior to study; stable doses of metformin or sulfonylureas for at least 3 months if on oral therapy	Adult patients aged ≥18 with type 2 diabetes requiring insulin treatment for at least 6 months and inadequate glycemic control (A1C ≥8.0%) who were free from symptoms of severe hyper- and hypoglycemia for 2 weeks; stable insulin dosing (no more than ±10%) for at least 2 months prior to study
Patient populations	N = 656, MDD: 12.2 years, Mean A1C: 9.1%	N = 499, MDD: 13.5 years, Mean A1C: 9.4%
Dosing	In addition to insulin: placebo TID or pramlintide 90 mcg BID, 120 mcg BID, or 60 mcg TID, administered 15 minutes before major meals. If used at baseline, metformin/sulfonylurea were continued throughout study	In addition to insulin: placebo or pramlintide 90 mcg BID, 120 mcg BID, or 90 mcg TID. If used at baseline, metformin/sulfonylurea were continued throughout study
Primary efficacy endpoint	Change in A1C at week 26	Change in A1C at week 26
Selected secondary and other endpoints	Change in body weight, change in insulin use	Change in body weight, change in insulin use

Abbreviations: BID, two times daily; MDD, mean duration of diabetes; QID, four times daily; TID, three times daily.

References:

1. Hollander PA, Levy P, Fineman MS et al. Pramlintide as an adjunct to insulin therapy improves long-term glycemic and weight control in patients with type 2 diabetes: a 1-year randomized controlled trial. *Diabetes Care*. 2003;26(3):784-790.

2. Data on File. 2991508. AstraZeneca Pharmaceuticals LP.