

SymlinPen™ 60 Wholesale Order Entry Number _____

SymlinPen™ 120 Wholesale Order Entry Number _____

SymlinPen™ Now Available

For Patients With Type 2 or Type 1 Diabetes Using Mealtime Insulin

Product Name

SYMLIN® injection

Established Name

pramlintide acetate

Indications and Usage

SYMLIN is given at mealtimes and is indicated for:

- Type 2 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin.
- Type 1 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

Sales Units to Trade

- **SymlinPen™ 60:** 1 carton containing 2 x 1.5-mL disposable, multidose pen-injector devices for doses of 15 mcg, 30 mcg, 45 mcg, and 60 mcg
- **SymlinPen™ 120:** 1 carton containing 2 x 2.7-mL disposable, multidose pen-injector devices for doses of 60 mcg and 120 mcg

Storage and Handling

- **SYMLIN pen-injectors not in use:** Refrigerate (36°F-46°F, 2°C-8°C) and protect from light. Do not freeze. Do not use if product has been frozen. Unused SYMLIN (opened or unopened) should not be used after the expiration (EXP) date printed on the carton and the label.
- **SYMLIN pen-injectors in use:** After first use, refrigerate or keep at a temperature not greater than 86°F (30°C) for 30 days. Use within 30 days, whether refrigerated or not.

SymlinPen™ 60

(pramlintide acetate)
pen-injector

SymlinPen™ 120

(pramlintide acetate)
pen-injector



Product Information

Description	NDC	Amylin Product Code	Minimum Dispensing Unit	WAC Price Per Carton
SymlinPen™ 60	66780-115-02	115-02	1 carton (2 pens/carton)	\$96.50
SymlinPen™ 120	66780-121-02	121-02	1 carton (2 pens/carton)	\$193.00

Please see the Important Safety Information, including the **Boxed Warning** regarding insulin-induced severe hypoglycemia and appropriate patient selection criteria, on reverse side. Please see the accompanying SYMLIN Prescribing Information.

Symlin®
(pramlintide acetate)
injection

SymlinPen™
(pramlintide acetate)
pen-injector

Important Safety Information for SYMLIN® (pramlintide acetate) Injection

WARNING

SYMLIN is used with insulin and has been associated with an increased risk of insulin-induced severe hypoglycemia, particularly in patients with type 1 diabetes. When severe hypoglycemia associated with SYMLIN use occurs, it is seen within 3 hours following a SYMLIN injection. If severe hypoglycemia occurs while operating a motor vehicle, heavy machinery, or while engaging in other high-risk activities, serious injuries may occur. Appropriate patient selection, careful patient instruction, and insulin dose adjustments are critical elements for reducing this risk.

INDICATIONS AND USAGE

SYMLIN is given at mealtimes and is indicated for:

- Type 2 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin.
- Type 1 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy.

CONTRAINDICATIONS

Hypersensitivity to SYMLIN or any of its components, including metacresol; confirmed diagnosis of gastroparesis; hypoglycemia unawareness.

WARNINGS

Patient Selection. Proper patient selection is critical to safe and effective use of SYMLIN. SYMLIN therapy should only be considered in patients with insulin-using type 2 or type 1 diabetes 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 an 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.

Hypoglycemia. SYMLIN alone does not cause hypoglycemia. However, SYMLIN is indicated to be co-administered with insulin therapy and in this setting SYMLIN increases the risk of insulin-induced severe hypoglycemia, particularly in patients with type 1 diabetes. Therefore, when introducing SYMLIN therapy, appropriate precautions need to be taken to avoid increasing the risk for insulin-induced severe hypoglycemia. These precautions include **frequent pre- and post-meal glucose monitoring combined with an initial 50% reduction in pre-meal doses of short-acting insulin.**

ADVERSE EVENTS

The most common adverse event was nausea, which decreased with time in most patients. For adverse events regarding severe hypoglycemia, see WARNINGS.

Please see the accompanying SYMLIN Prescribing Information.

Further Product Information

For questions regarding SYMLIN, please call Amylin Customer Support at **1-800-349-8919** or visit **www.SYMLIN.com**

Reimbursement Information

Amylin Reimbursement Hotline: **1-800-330-7647**

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