

1 **Medication Guide**

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3 **SYMLIN[®] (SĪM-lĭn)**
4 **(pramlintide acetate) Injection**

5 Read the Medication Guide that comes with SYMLIN before you start using it and each time
6 you get a refill. There may be new information. This Medication Guide does not take the place
7 of talking to your doctor about your medical condition or treatment.

8 **What is the most important information I should know about SYMLIN?**

- 9 • **SYMLIN is used with insulin to lower blood sugar, especially high blood sugar that**
10 **happens after meals.**
- 11 • **SYMLIN is given at mealtimes. The use of SYMLIN does not replace your daily**
12 **insulin but may lower the amount of insulin you need, especially before meals.**
- 13 • **Even when SYMLIN is carefully added to your mealtime insulin therapy, your**
14 **blood sugar may drop too low, especially if you have type 1 diabetes. If this low**
15 **blood sugar (severe hypoglycemia) happens, it is seen within 3 hours after a**
16 **SYMLIN injection. Severe low blood sugar makes it hard to think clearly, drive a**
17 **car, use heavy machinery or do other risky activities where you could hurt yourself**
18 **or others.**
- 19 • **SYMLIN should only be used by people with type 1 and type 2 diabetes who:**
- 20 • already use their insulin as prescribed, but still need better blood sugar control.
- 21 • will follow their doctor's instructions exactly.
- 22 • will follow up with their doctor often.
- 23 • will test their blood sugar levels before and after every meal, and at bedtime.
- 24 • understand how to adjust SYMLIN and insulin doses.

25 **What is SYMLIN?**

26 SYMLIN is an injectable medicine for adults with type 1 and type 2 diabetes to control blood
27 sugar. SYMLIN slows down the movement of food through your stomach. This affects how fast
28 sugar enters your blood after eating. SYMLIN is always used with insulin to help lower blood
29 sugar during the 3 hours after meals.

30 **Who should not use SYMLIN?**

31 **Do not use SYMLIN if you:**

- 32 • cannot tell when your blood sugar is low (hypoglycemia unawareness).
- 33 • have a stomach problem called gastroparesis. This is when your stomach does not empty as
34 fast as it should.
- 35 • are allergic to SYMLIN or any ingredients in SYMLIN. See the end of this Medication
36 Guide for a complete list of ingredients.

37 **SYMLIN has not been studied in children.**

38 **What should I tell my doctor before starting SYMLIN?**

39 **Tell your doctor about all of your medical conditions including if you:**

- 40 • **are pregnant or planning to become pregnant.** It is not known if SYMLIN can harm your
41 unborn baby. You and your doctor will decide how to best control your blood sugar levels
42 during pregnancy.
- 43 • **are breastfeeding.** It is not known if SYMLIN passes into your milk and if it can harm your
44 baby. You and your doctor will decide the best way to feed your baby if you are using
45 SYMLIN.

46 **Keep a list of all the medicines you take. Tell your doctor about all the medicines you take**
47 **including prescription and non-prescription medicines, vitamins, and herbal supplements.**
48 SYMLIN can slow down how other medicines pass through your stomach and may affect how
49 much of them get into your body. Therefore, you may have to change the times you take certain
50 medicines.

51 **How should I use SYMLIN?**

- 52 • **You must use SYMLIN exactly as prescribed. The amount of SYMLIN you use will**
53 **depend on whether you have type 1 or type 2 diabetes.** You and your doctor will decide if
54 you can use SYMLIN.
- 55 • **Never mix SYMLIN and insulin.** You must use different syringes for SYMLIN and insulin
56 because insulin can affect SYMLIN when the two are mixed together.
- 57 • Injecting SYMLIN is similar to injecting insulin. **Inject SYMLIN under the skin**
58 **(subcutaneously) of your stomach area (abdomen) or upper leg (thigh).** Inject SYMLIN
59 at a site that is more than 2 inches away from your insulin injection. Allow SYMLIN to
60 warm to room temperature before injecting. Use a U-100 insulin syringe (best to use 0.3 mL
61 [0.3 cc] size) to draw-up and inject SYMLIN. Always use a new syringe and needle for each
62 SYMLIN injection.
- 63 • The dose of SYMLIN that your doctor prescribes should be one in the table below. Use this
64 table to match your SYMLIN dose to insulin syringe units:

Find Your Dose in micrograms (µg)	Draw Up This Amount in U-100 Insulin Syringe (units)
15	2.5
30	5.0
45	7.5
60	10.0
120	20.0

- 65
- 66 • Do not use SYMLIN if the liquid in the vial looks cloudy.
 - 67 • If you take more than your prescribed dose of SYMLIN, you may get nauseous or vomit, and
68 you may not be able to eat the amount of food you usually eat. Pay careful attention to the

69 amount of insulin you use at this time as you may be at more risk for low blood sugar.
70 Contact your doctor for guidance.

- 71 • If you miss or forget a dose of SYMLIN, wait until the next meal and take your usual dose of
72 SYMLIN at that meal. Do not take more than your usual dose of SYMLIN.

73 **Using SYMLIN and insulin with Type 2 Diabetes (see the Table above)**

- 74 1. Start SYMLIN at 60 µg injected under your skin, just before major meals. A major meal
75 must have at least 250 calories or 30 grams of carbohydrate.
- 76 2. Reduce your rapid-acting or short-acting insulin doses before meals by **50 percent**,
77 including fixed-mix insulins such as 70/30. This means half of the dose you usually use.
- 78 3. You must check your blood sugar before and after every meal and at bedtime.
- 79 4. Increase your dose of SYMLIN to 120 µg on your doctor's instructions if you have not
80 had any nausea for 3 days or more.
- 81 5. Tell your doctor right away if you have nausea with the 120 µg dose. Your doctor will
82 tell you how to adjust your dose of SYMLIN.
- 83 6. Your doctor may make changes to your insulin doses to better control your blood sugar
84 once you are using the 120 µg dose of SYMLIN. All insulin changes should be directed
85 by your doctor.

86 **Using SYMLIN and insulin with Type 1 Diabetes (see the Table above)**

- 87 1. Start SYMLIN at 15 µg injected under your skin, just before major meals. A major meal
88 must have at least 250 calories or 30 grams of carbohydrate.
- 89 2. When starting SYMLIN, reduce your rapid-acting or short-acting insulin doses before
90 meals by **50 percent**, including fixed-mix insulins such as 70/30. This means half of the
91 dose you usually use. All insulin changes should be directed by your doctor.
- 92 3. You must check your blood sugar before and after every meal and at bedtime.
- 93 4. Increase your dose of SYMLIN to 30 µg on your doctor's instructions if you have not
94 had any nausea for 3 days or more. If you have nausea with SYMLIN at 30 µg, call your
95 doctor right away. Your doctor may decide that you should stop SYMLIN.
- 96 5. Increase your dose of SYMLIN to 45 µg on your doctor's instructions if you have not
97 had any nausea for 3 days or more while using the 30 µg dose.
- 98 6. Increase your dose of SYMLIN to 60 µg on your doctor's instructions if you have not
99 had any nausea for 3 days or more while using the 45 µg dose.
- 100 7. Call your doctor right away if you are bothered with nausea on the 45 µg or 60 µg dose.
101 Your doctor may decide that you should reduce SYMLIN to the 30 µg dose.
- 102 8. Your doctor may make changes to your insulin doses to better control your blood sugar
103 once you are on a dose of SYMLIN that is right for you. All insulin changes should be
104 directed by your doctor.

105 **Staying on SYMLIN**

- 106 • Once you reach your recommended dose of SYMLIN, talk to your doctor about changing
107 your insulin doses to better control your blood sugar. You may have to increase your
108 long-acting insulin to prevent high blood sugar (hyperglycemia) between meals. **Insulin**
109 **changes should be directed by your doctor based on blood sugar testing.**
- 110 • Call your doctor if nausea or low blood sugar continues while on your recommended dose of
111 SYMLIN. Low blood sugar that happens often is a warning sign of possible severe low
112 blood sugar, especially if you have type 1 diabetes.
- 113 • **If you stop taking SYMLIN for any reason, such as surgery or illness, call your doctor.**
114 **SYMLIN should be restarted as described above in “How should I use SYMLIN?”**

115 **When should I not use SYMLIN?**

116 **Do not use SYMLIN if:**

- 117 • Your blood sugar is too low.
- 118 • You do not plan to eat. Do not inject SYMLIN if you skip a meal.
- 119 • You plan to eat a meal with less than 250 calories or 30 grams of carbohydrate.
- 120 • You are sick and can't eat your usual meal.
- 121 • You are having surgery or a medical test where you cannot eat.
- 122 • You are pregnant or breastfeeding and have not talked to your doctor.

123 Talk to your doctor if you have any of these conditions.

124 **What should I avoid while taking SYMLIN?**

- 125 • Do not drive or operate dangerous machinery until you know how SYMLIN affects your
126 blood sugar. Low blood sugar makes it hard to think clearly, drive a car, use heavy
127 machinery or do other risky activities where you could hurt yourself or others. Discuss with
128 your doctor what activities you should avoid.
- 129 • Alcohol may increase the risk of low blood sugar.
- 130 • **Your doctor will tell you which medicines you can take while using SYMLIN. Do not**
131 **take other medicines that slow stomach emptying.**

132 Always have fast-acting sugar (such as hard candy, glucose tablets, juice) or glucagon available
133 to treat low blood sugar.

134 **What are the possible side effects of SYMLIN?**

135 **Low blood sugar (hypoglycemia)**

- 136 • **SYMLIN is used with insulin to lower your blood sugar, but your blood sugar may**
137 **drop too low, especially if you have type 1 diabetes.** See “What is the most important
138 information I should know about SYMLIN?”

- 139 • When starting SYMLIN, reduce your doses of insulin before meals as recommended by your
140 doctor to reduce the chance of low blood sugar. You and your doctor should talk about a
141 plan to treat low blood sugar. You should have fast-acting sugar (such as hard candy,
142 glucose tablets, juice) or glucagon with you at all times. Call your doctor if you have low
143 blood sugar more often than normal or severe low blood sugar.

144 **Your chance for low blood sugar is higher if you:**

- 145 • do not reduce your insulin dose before meals at the beginning of SYMLIN treatment, as
146 directed by your doctor.
- 147 • use more SYMLIN or insulin than prescribed by your doctor.
- 148 • change your insulin dose without checking your blood sugar.
- 149 • eat less food than your usual meal.
- 150 • are sick and cannot eat.
- 151 • are more active than usual.
- 152 • have a low blood sugar level before eating.
- 153 • drink alcohol.

154 **Nausea:** Nausea is the most common side effect with SYMLIN. Mild nausea is more likely
155 during the first weeks after starting SYMLIN and usually does not last long. It is very important
156 to start SYMLIN at a low dose and increase it as directed by your doctor. See “How should I
157 use SYMLIN?” If nausea continues or bothers you, call your doctor right away.

158 **Other Side Effects:** SYMLIN also may cause the following side effects: decreased appetite,
159 vomiting, stomach pain, tiredness, dizziness, or indigestion.

160 SYMLIN also can cause reactions at the injection site including redness, minor bruising, or pain.
161 Follow the directions under “How should I use SYMLIN?” to reduce the chance of an injection
162 site reaction.

163 Tell your doctor if you have any side effects that bother you or that do not go away.

164 These are not all the side effects with SYMLIN. Ask your doctor or pharmacist for more
165 information.

166 **How should I store SYMLIN?**

- 167 • Store SYMLIN vials in the refrigerator until you open them.
- 168 • Opened vials can be refrigerated or kept at room temperature for up to 28 days. Any opened
169 vial should be thrown away after 28 days, even if it still has medicine in it.
- 170 • Throw away any vial that is out-of-date, has been frozen, heated above room temperature
171 (77°F/25°C) or left at room temperature for more than 28 days.
- 172 • **Keep SYMLIN and all medicines out of the reach of children.**

173 **General information about the safe and effective use of SYMLIN**

174 Medicines are sometimes prescribed for conditions other than those described in a Medication
175 Guide. Do not use SYMLIN for a condition for which it was not prescribed. Do not give
176 SYMLIN to other people, even if they have the same symptoms that you have. It may harm
177 them.

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179 This Medication Guide summarizes the most important information about SYMLIN. If you
180 would like more information, talk with your doctor. You can ask your doctor or pharmacist for
181 information about SYMLIN that is written for health professionals.

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183 More information on SYMLIN can be found at <http://www.symlin.com>.
184 SYMLIN Customer Service is available 24 hours a day at 1-800-349-8919.

185 **What are the ingredients in SYMLIN?**

186 **Active ingredient:** pramlintide acetate

187 **Inactive ingredients:** metacresol, D-mannitol, acetic acid, and sodium acetate.

188
189 *This draft Medication Guide is pending approval by the U.S. Food and Drug Administration.*

190
191 Literature issued March 2005.

192
193 **Manufactured for Amylin Pharmaceuticals, Inc.**
194 **San Diego CA 92121, USA**
195 **1-800-349-8919**
196 **<http://www.symlin.com>**

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