

Medication Guide

SYMLIN[®] (SĪM-lĭn) **(pramlintide acetate) injection**

Read the Medication Guide and the “Patient Instructions for Use” that come with your SYMLIN product before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment.

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

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

What is SYMLIN?

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

Who should not use SYMLIN?

Do not use SYMLIN if you:

- cannot tell when your blood sugar is low (hypoglycemia unawareness).
- have a stomach problem called gastroparesis. This is when your stomach does not empty as fast as it should.

- are allergic to SYMLIN or any ingredients in SYMLIN. See the end of this Medication Guide for a complete list of ingredients.

SYMLIN has not been studied in children.

What should I tell my doctor before starting SYMLIN?

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

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

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

How should I use SYMLIN?

- **You must use SYMLIN exactly as prescribed. The amount of SYMLIN you use will depend on whether you have type 2 or type 1 diabetes.** You and your doctor will decide if you can use SYMLIN.
- It is important for you to carefully read, understand and follow the “Patient Instructions for Use” that comes along with this Medication Guide and your SYMLIN.
- **SYMLIN is available in vials and two SymlinPen[®] pen-injectors. Your doctor will prescribe the type of SYMLIN that is right for you.**
 - If you have been using the SYMLIN vial with an insulin syringe and you are changing to the SymlinPen[®] pen-injector: **Your doctor will prescribe the SymlinPen[®] pen-injector that is right for you, tell you how much SYMLIN to inject and when to inject it.**
 - **It is important that you understand how to inject the right SYMLIN dose. Read the “Patient Instructions for Use” carefully BEFORE giving your first dose with the SymlinPen[®] pen-injector. The SYMLIN in the pen-injector is a different strength than the SYMLIN in the vial.**
- The way you inject SYMLIN is similar to the way you inject insulin. **Inject SYMLIN under the skin (subcutaneously) of your stomach area (abdomen) or upper leg (thigh).** Inject SYMLIN at a site that is more than 2 inches away from your insulin injection. Do not inject SYMLIN and insulin in the same site.
- To help reduce the chances of getting a reaction at the injection site, allow SYMLIN to come to room temperature before injecting.
- Use a new needle for each SYMLIN injection.

- **Never mix SYMLIN and insulin.** Insulin can affect SYMLIN when the two are mixed together.
- Do not use SYMLIN if the liquid looks cloudy.
- If you take more than your prescribed dose of SYMLIN, you may get nauseous or vomit, and you may not be able to eat the amount of food you usually eat. If you take more SYMLIN than your prescribed dose, pay careful attention to the amount of insulin you use because you may be at more risk for low blood sugar. Contact your doctor for guidance.
- If you miss or forget a dose of SYMLIN, wait until the next meal and take your usual dose of SYMLIN at that meal. Do not take more than your usual dose of SYMLIN.

Using SYMLIN and insulin with Type 2 Diabetes

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

Using SYMLIN and insulin with Type 1 Diabetes

1. Start SYMLIN at 15 mcg injected under your skin, just before major meals. A major meal must have at least 250 calories or 30 grams of carbohydrate.
2. When starting SYMLIN, reduce your rapid-acting or short-acting insulin, including fixed-mix insulin such as 70/30, used before meals by **50 percent**. This means half of the dose you usually use. All insulin changes should be directed by your doctor.
3. You must check your blood sugar before and after every meal and at bedtime.
4. Increase your dose of SYMLIN to 30 mcg on your doctor's instructions if you have not had any nausea for 3 days or more. If you have nausea with SYMLIN at 30 mcg, call your doctor right away. Your doctor may decide that you should stop SYMLIN.
5. Increase your dose of SYMLIN to 45 mcg on your doctor's instructions if you have not had any nausea for 3 days or more while using the 30 mcg dose.
6. Increase your dose of SYMLIN to 60 mcg on your doctor's instructions if you have not had any nausea for 3 days or more while using the 45 mcg dose.

7. Call your doctor right away if you are bothered with nausea on the 45 mcg or 60 mcg dose. Your doctor may decide that you should reduce SYMLIN to the 30 mcg dose.
8. Your doctor may make changes to your insulin doses to better control your blood sugar once you are on a dose of SYMLIN that is right for you. All insulin changes should be directed by your doctor.

Staying on SYMLIN

- Once you reach your recommended dose of SYMLIN, talk to your doctor about changing your insulin doses to better control your blood sugar. You may have to increase your long-acting insulin to prevent high blood sugar (hyperglycemia) between meals. **Insulin changes should always be directed by your doctor based on blood sugar testing.**
- Call your doctor if nausea or low blood sugar continues while on your recommended dose of SYMLIN. Low blood sugar that happens often is a warning sign of possible severe low blood sugar, especially if you have type 1 diabetes.
- **If you stop taking SYMLIN for any reason, such as surgery or illness, talk to your doctor about how to re-start SYMLIN.**

When should I not use SYMLIN?

Do not use SYMLIN if:

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

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

What should I avoid while taking SYMLIN?

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

What are the possible side effects of SYMLIN?

Low blood sugar (hypoglycemia)

- **SYMLIN is used with insulin to lower your blood sugar, but your blood sugar may drop too low, especially if you have type 1 diabetes.** See “What is the most important information I should know about SYMLIN?”
- When starting SYMLIN, reduce your doses of insulin before meals as recommended by your doctor to reduce the chance of low blood sugar. You and your doctor should talk about a plan to treat low blood sugar. You should have fast-acting sugar (such as hard candy, glucose tablets, juice) or glucagon with you at all times. Call your doctor if you have low blood sugar more often than normal or severe low blood sugar.

Your chance for low blood sugar is higher if you:

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

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

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

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

SYMLIN also can cause reactions at the injection site including redness, minor bruising, or pain. See the detailed “Patient Instructions for Use.” Follow the directions under “How should I use SYMLIN?” to reduce the chance of an injection site reaction.

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

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

How should I store SYMLIN?

- Store SYMLIN that has not been opened in the refrigerator, between 36°F to 46°F (2°C to 8°C), until you are ready to use it. Protect SYMLIN from light.
- After a vial or pen-injector has been used for the first time, it can be refrigerated or kept at a temperature up to 86°F (30°C) for 30 days. Do not leave **above** 86°F (30°C). Any vial or pen-injector in use should be thrown away after 30 days, even if it still has medicine in it.
- Unused SYMLIN (opened or unopened) should not be used after the expiration (EXP) date printed on the carton and the label.
- **Do not freeze SYMLIN. Do not use SYMLIN if it has been frozen.**

Keep SYMLIN and all medicines out of the reach of children.

General information about the safe and effective use of SYMLIN

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

This Medication Guide summarizes the most important information about SYMLIN. Also see the “Patient Instructions for Use” on using the SymlinPen[®] pen-injector or vial. You can ask your doctor for more about SYMLIN, including information that is written for doctors.

More information on SYMLIN can be found at <http://www.SYMLIN.com>.

SYMLIN Customer Service is available 24 hours a day at 1-800-349-8919.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What are the ingredients in SYMLIN?

Active ingredient: pramlintide acetate

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

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Literature Revised July 2008

Manufactured for Amylin Pharmaceuticals, Inc.

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<http://www.SYMLIN.com>

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