

Medication Guide **Rx Only**
SOLIQUA® 100/33 (So - lee - kwa)
(insulin glargine and lixisenatide injection) for subcutaneous use

What is the most important information I should know about SOLIQUA 100/33?

Do not share your SOLIQUA 100/33 pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

SOLIQUA 100/33 can cause serious side effects including inflammation of the pancreas (pancreatitis), which may be severe and lead to death.

Before using SOLIQUA 100/33, tell your healthcare provider if you have had:

- pancreatitis
- stones in your gallbladder (cholelithiasis)
- a history of alcoholism

These medical problems may make you more likely to get pancreatitis.

Stop taking SOLIQUA 100/33 and call your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe, and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

What is SOLIQUA 100/33?

SOLIQUA 100/33 is an injectable prescription medicine that contains 2 diabetes medicines, insulin glargine and lixisenatide, that may improve blood sugar (glucose) control in adults with type 2 diabetes when used with diet and exercise in people who are not controlled with long-acting (basal) insulin (less than 60 units daily) or lixisenatide.

- SOLIQUA 100/33 has not been studied in people with a history of pancreatitis.
- SOLIQUA 100/33 is not recommended for people who also take lixisenatide or other medicines called GLP-1 receptor agonists.
- SOLIQUA 100/33 is not for use in people with type 1 diabetes or people with diabetic ketoacidosis.
- SOLIQUA 100/33 has not been studied in people who have a stomach problem that causes slow emptying of the stomach (gastroparesis). SOLIQUA 100/33 is not for people with slow emptying of the stomach.
- SOLIQUA 100/33 has not been studied in people who also take a short-acting (prandial) insulin.
- **It is not known if SOLIQUA 100/33 is safe and effective in children under 18 years of age.**

Who should not use SOLIQUA 100/33?

Do not use SOLIQUA 100/33 if you:

- are having an episode of low blood sugar (hypoglycemia).
- are allergic to insulin glargine, lixisenatide or any of the other ingredients in SOLIQUA 100/33. See the end of this Medication Guide for a complete list of ingredients in SOLIQUA 100/33.

Symptoms of a severe allergic reaction with SOLIQUA 100/33 may include swelling of your face, lips, tongue, or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy and very rapid heartbeat.

Before using SOLIQUA 100/33, tell your healthcare provider about all your medical conditions including if you:

- have or have had symptoms of acute pancreatitis, stones in your gallbladder, or a history of alcoholism.
- have or have had liver or kidney problems.
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take a TZD (thiazolidinediones).
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- are pregnant, or plan to become pregnant. It is not known if SOLIQUA 100/33 will harm your unborn baby. Tell your healthcare provider if you are pregnant or plan to become pregnant while using SOLIQUA 100/33.
- are breastfeeding or plan to breastfeed. It is not known if SOLIQUA 100/33 passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby while you use SOLIQUA 100/33.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOLIQUA 100/33 may affect the way some medicines work and some medicines may affect the way SOLIQUA 100/33 works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use SOLIQUA 100/33?

- Read all the detailed **Instructions for Use** that come with SOLIQUA 100/33 for instructions on using the SOLIQUA 100/33 pen and injecting SOLIQUA 100/33.
- Use SOLIQUA 100/33 exactly as your healthcare provider tells you to.
- Do not change your dose unless your healthcare provider has told you to change your dose.
- Your healthcare provider should teach you how to inject SOLIQUA 100/33 before you use it for the first time. If you have questions or do not understand the instructions, talk to your healthcare provider.
- Take SOLIQUA 100/33 only 1 time each day within 1 hour before the first meal of the day.
- If you miss a dose of SOLIQUA 100/33, take your next scheduled dose at your regular time. **Do not** take an extra dose or increase your dose to make up for the missed dose.
- Check the label on the SOLIQUA 100/33 pen each time you give your injection to make sure you are using the correct medicine.
- **Do not take more than 60 units of SOLIQUA 100/33 each day.** SOLIQUA 100/33 contains two medicines: insulin glargine and lixisenatide. If you take too much SOLIQUA 100/33, it can cause severe nausea and vomiting. Do not take SOLIQUA 100/33 with other GLP-1 receptor agonists. If you take too much SOLIQUA 100/33, call your healthcare provider or go to the nearest hospital emergency room right away.
- Only use SOLIQUA 100/33 that is clear, colorless to almost colorless. If you see small particles, return it to your pharmacy for a replacement.
- Change (rotate) your injection sites within the area you chose with each dose. Do not use the same spot for each injection to avoid skin thickening or pits at the injection site (lipodystrophy).
- Inject your dose of SOLIQUA 100/33 under the skin (subcutaneously) of your abdomen, thigh or upper arm. Do not use SOLIQUA 100/33 in an insulin pump or inject SOLIQUA 100/33 into your vein (intravenously) or muscle (intramuscularly).
- **Do not** mix SOLIQUA 100/33 in any other type of insulin or liquid medicine prior to injection.
- **Do not** remove SOLIQUA 100/33 from the throw away (disposable) prefilled pen with a syringe.
- **Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.**
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

Your dose of SOLIQUA 100/33 may need to change because of a change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

What are the possible side effects of SOLIQUA 100/33?

SOLIQUA 100/33 may cause serious side effects including:

- See “**What is the most important information I should know about SOLIQUA 100/33?**”
- **Severe allergic reactions.** Severe allergic reactions can happen with SOLIQUA 100/33. Stop taking SOLIQUA 100/33 and get medical help right away if you have any symptoms of a severe allergic reaction. See “**Who should not use SOLIQUA 100/33?**”
- **Low blood sugar (hypoglycemia). Your risk for getting low blood sugar is higher if you take another medicine that can cause low blood sugar.** Signs and symptoms of low blood sugar include:

- headache
- weakness
- fast heartbeat
- dizziness
- irritability
- feeling jittery
- drowsiness
- hunger
- confusion
- sweating

Talk with your healthcare provider about how to treat low blood sugar.

- **Kidney problems (kidney failure).** In people who have kidney problems, the occurrence of diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.
- **Low potassium in your blood (hypokalemia).**
- **Heart failure.** Taking certain diabetes pills called TZDs with SOLIQUA 100/33 may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with SOLIQUA 100/33. Your healthcare provider should monitor you closely while you are taking TZDs with SOLIQUA 100/33. Tell your healthcare provider if you have any new or worse symptoms of heart failure including shortness of breath, swelling of your ankles or feet, sudden weight gain. Treatment with TZDs and SOLIQUA 100/33 may need to be changed or stopped by your healthcare provider if you have new or worse heart failure.

The most common side effects of SOLIQUA 100/33 may include:

- low blood sugar (hypoglycemia)
- nausea
- headache
- stuffy or runny nose and sore throat
- allergic reactions
- diarrhea
- upper respiratory tract infection

Nausea and diarrhea usually happen more often when you start using **SOLIQUA 100/33**.

These are not all the possible side effects of SOLIQUA 100/33.

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

How should I store SOLIQUA 100/33?

- Store your new, unused SOLIQUA 100/33 SoloStar[®] pen in the refrigerator at 36°F to 46°F (2°C to 8°C). Protect the pen from light.
- After first use, store your SOLIQUA 100/33 pen at room temperature no higher than 77°F (25°C).
- Do not freeze SOLIQUA 100/33 pens and do not use SOLIQUA 100/33 if it has been frozen.
- Replace the pen cap after each use to protect from light.
- After first use, use the SOLIQUA 100/33 pen for up to 28 days. Throw away the used SOLIQUA 100/33 pen after 28 days, even if there is some medicine left in the pen.
- Do not use SOLIQUA 100/33 past the expiration date printed on the label of the carton and pen.
- Do not store the SOLIQUA 100/33 pen with the needle attached. If the needle is left on, this might lead to contamination and cause air bubbles which might affect your dose of medicine.
- See the **Instructions for Use** about the right way to throw away the SOLIQUA 100/33 pen.
- **Keep your SOLIQUA 100/33 pen, pen needles, and all medicines out of the reach of children.**

General information about the safe and effective use of SOLIQUA 100/33.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. **Do not** use SOLIQUA 100/33 for a condition for which it was not prescribed. Do not give SOLIQUA 100/33 to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about SOLIQUA 100/33 that is written for health professionals.

What are the ingredients in SOLIQUA 100/33?

Active ingredients: insulin glargine and lixisenatide

Inactive ingredients: 3 mg of methionine, 2.7 mg of metacresol, 20 mg of glycerol, 30 mcg of zinc, hydrochloric acid, sodium hydroxide and water for injection.

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For more information, go to www.soliqua100-33.com or call sanofi-aventis at 1-800-633-1610.

This Medication Guide has been approved by the U.S. Food and Drug Administration
Approved: October 2017

GLX-MG-SL-OCT17