

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?

SOLIQUA 100/33 can cause serious side effects including inflammation of the pancreas (pancreatitis).

Stop using SOLIQUA 100/33 and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without nausea or vomiting. You may feel the pain from your abdomen to your back.

What is SOLIQUA 100/33?

SOLIQUA 100/33 is an injectable prescription medicine that contains 2 diabetes medicines, insulin glargine and lixisenatide, that is used along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes.

- SOLIQUA 100/33 is not recommended for people who also take lixisenatide or other medicines called glucagon-like peptide-1 receptor agonists (GLP-1) receptor agonists.
- SOLIQUA 100/33 is not for use in people with diabetic ketoacidosis.
- 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.

Who should not use SOLIQUA 100/33?

Do not use SOLIQUA 100/33 if you:

- are having an episode of low blood sugar (hypoglycemia).
- have had a serious allergic reaction 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. See "What are the possible side effects of SOLIQUA 100/33?" for symptoms of a serious allergic reaction.

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

- have or have had problems with your pancreas.
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take thiazolidinediones (TZDs).
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- are taking certain medicines called glucagon-like peptide-1 receptor agonists (GLP-1 receptor agonists).
- are scheduled to have surgery or other procedures that use general anesthesia or deep sleepiness (deep sedation).
- 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.

Before using SOLIQUA 100/33, talk to your healthcare provider about low blood sugar and how to manage it.

Especially tell your healthcare provider if you take:

- antibiotics or the pain reliever, acetaminophen. Take these medicines at least 1 hour before using SOLIQUA 100/33. If you must take these medicines, take them with a meal or a snack. You should not take these medicines at the same time that you take SOLIQUA 100/33.
- birth control pills that are taken by mouth (oral contraceptives). SOLIQUA 100/33 may lower the amount of the medicine in your blood from your birth control pills and they may not work as well to prevent pregnancy. Take your birth control pill at least 1 hour before your injection of SOLIQUA 100/33 or at least 11 hours after your SOLIQUA 100/33 injection.

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 the **Instructions for Use** that comes with 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.
- **Your healthcare provider should show you how to use SOLIQUA 100/33 before you use it for the first time.**
- 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).
- **Use 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 and colorless to almost colorless. If you see small particles, return it to your pharmacy for a replacement.

- **Change (rotate) your injection site within the area you choose with each dose** to reduce your risk of getting pits in skin or thickened skin (lipodystrophy) and skin with lumps (localized cutaneous amyloidosis) at the injection sites.
 - **Do not** use the exact same spot for each injection.
 - **Do not** inject where the skin has pits, is thickened, or has lumps.
 - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **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.
- If you take too much SOLIQUA 100/33, call your healthcare provider or the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

What should I avoid while taking SOLIQUA 100/33?

While taking SOLIQUA 100/33 do not:

- drive or operate heavy machinery, until you know how SOLIQUA 100/33 affects you.
- drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

What are the possible side effects of SOLIQUA 100/33? SOLIQUA 100/33 can cause serious side effects including:

- See "What is the most important information I should know about SOLIQUA 100/33?"
- **severe allergic reactions.** Stop taking SOLIQUA 100/33 and get medical help right away if you have any symptoms of a severe allergic reaction including
 - swelling of your face, lips, tongue or throat
 - problems breathing or swallowing
 - severe rash or itching
 - fainting or feeling dizzy
 - very rapid heartbeat
- **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 may include:**
 - Dizziness or light-headedness
 - sweating
 - confusion or drowsiness
 - headache
 - blurred vision
 - slurred speech
 - shakiness
 - fast heartbeat
 - anxiety, irritability, or mood changes
 - hunger
 - weakness
 - feeling jittery

- **dehydration leading to kidney problems.** Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.
- **Severe stomach problems.** Stomach problems, sometimes severe, have been reported in people who use SOLIQUA 100/33. Tell your healthcare provider if you have stomach problems that are severe or will not go away.
- **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, or sudden weight gain. Treatment with TZDs and SOLIQUA 100/33 may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.
- **gallbladder problems.** Gallbladder problems have happened in some people who take SOLIQUA 100/33. Tell your healthcare provider right away if you get symptoms of gallbladder problems which may include:
 - pain in your upper stomach (abdomen)
 - fever
 - yellowing of skin or eyes (jaundice)
 - clay-colored stools
- **food or liquid getting into the lungs during surgery or other procedures that use general anesthesia or deep sleepiness (deep sedation).** SOLIQUA 100/33 may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking SOLIQUA 100/33 before you are scheduled to have surgery or other procedures.

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

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

Talk to your healthcare provider about any side effect that bothers you or does not go away.

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 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 carton and pen label.
- 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: glycerol (20 mg), metacresol (2.7 mg), methionine (3 mg), zinc (30 mcg) and Water for Injection, USP. Hydrochloric acid and/or sodium hydroxide are added as needed to adjust the pH.

Manufactured by: sanofi-aventis U.S. LLC, Morristown, NJ
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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. Revised: March 2026