

SOLIQUA® SoloStar® solution for injection in a pre-filled pen

Insulin glargine + lixisenatide
(100 units/ml + 50 micrograms/ml)

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What Soliqua is used for

Soliqua is used to treat adults with type 2 diabetes, to help control blood sugar levels when they are too high, as an adjunct to diet and exercise. It is given with metformin with or without SGLT-2 inhibitors, when other medicines are not enough on their own to control your blood sugar levels.

If you use another anti-diabetic medicine, discuss with your doctor whether you should stop using that medicine when starting Soliqua.

How Soliqua works

Soliqua is an injectable diabetes medicine that contains two active substances:

- insulin glargine: a long-acting type of insulin which helps control blood sugar (glucose) throughout the day.
- lixisenatide: a “GLP-1 analogue” that helps the body produce its own additional insulin in response to increases in blood sugar, and slows the absorption of sugar from foods.

Before you use Soliqua

-When you must not use it

If you are allergic to insulin glargine or lixisenatide or to any of the other ingredients of this medicine.

-Before you start to use it

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Soliqua if:

- you have type 1 diabetes, as Soliqua is used for type 2 diabetes and this medicine will not be right for you.
- you have diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to use glucose because there is not enough

insulin) since this medicine will not be right for you.

- you have a severe stomach or gut problem such as a disease of the muscles of the stomach called “gastroparesis” which results in delayed stomach emptying. Since Soliqua may cause stomach side effects, the medicine has not been studied in patients with severe stomach or gut problems. Please see the information regarding medicines that should not stay too long in your stomach in the section Taking other medicines.
- you have severe kidney disease or you are on dialysis as the use of this medicine will not be recommended.
- if you know that you are due to have surgery where you will be under anesthesia (sleeping), please tell your doctor that you are taking [Soliqua].

Follow closely your doctor's instructions for dose, monitoring (blood and urine tests), diet and physical activity (physical work and exercise) and injection technique.

Children and adolescents

There is no experience with Soliqua in children and adolescents aged less than 18 years; therefore, the use of Soliqua is not recommended in this age group.

Pregnancy and breast-feeding

Soliqua should not be used during pregnancy. It is not known if Soliqua harms your unborn child.

Soliqua should not be used if breast-feeding. It is not known if Soliqua passes into your milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Having too low or too high blood sugar can affect your ability to drive and use tools or machines. Your concentration may be affected. This could be dangerous to yourself and others.

Ask your doctor whether you can drive if:

- Your blood sugar is often too low.
- You find it hard to recognise when your blood sugar is too low.

-Taking other medicines

Some medicines can change your blood sugar level. This may mean your Soliqua dose has to change. Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Your blood sugar level may fall (hypoglycaemia) if you take:

- Any other medicine to treat diabetes.
- Disopyramide, for some heart problems.
- Fluoxetine, for depression.
- Sulphonamide antibiotics, to treat infections.
- Fibrates, for lowering high levels of blood fats.
- Monoamine oxidase inhibitors (MAOIs), for depression or Parkinson's disease.
- Angiotensin converting enzyme (ACE) inhibitors, for heart problems or high blood pressure.
- Medicines to relieve pain and lower fever, such as pentoxifylline, propoxyphene and salicylates (such as acetylsalicylic acid).
- Pentamidine, for some parasite infections. This may cause too low blood sugar which is sometimes followed by too high blood sugar.

Your blood sugar level may rise (hyperglycaemia) if you take:

- Corticosteroids such as cortisone and prednisolone, for inflammation.
- Danazol, for endometriosis.
- Diazoxide, for high blood pressure.
- Protease inhibitors, for HIV.
- Diuretics, for high blood pressure or fluid retention.
- Glucagon, for very low blood sugar.
- Isoniazid, for tuberculosis.
- Somatropin, a growth hormone.
- Thyroid hormones, for thyroid gland problems.
- Oestrogens and progestogens, such as in the contraceptive pill for birth control or use of oestrogens for bone loss (osteoporosis).

- Clozapine, olanzapine and phenothiazine derivatives, for mental health problems.
- Sympathomimetic medicines such as epinephrine (adrenaline), salbutamol and terbutaline, for asthma.

Your blood sugar level may either rise or fall if you take:

- Beta-blockers or clonidine, for high blood pressure.
- Lithium salts, for mental health problems.

Medicine that may reduce warning signs of low blood sugar

Beta-blockers and some other medicines (such as clonidine, guanethidine, reserpine, for high blood pressure) may make it harder to recognise warning signs of your low blood sugar levels (hypoglycaemia). It can even hide or stop the first signs that your blood sugar is too low.

Warfarin or other anticoagulants

Tell your doctor if you are taking warfarin or other anticoagulants (medicines used to prevent clotting of the blood) as you might need to have more frequent blood tests (called 'International Normalised Ratio' or INR test) to check your blood clotting.

Soliqua with alcohol

Your blood sugar level may either rise or fall if you drink alcohol. You should check your blood sugar level more often.

How to use Soliqua

Always use this medicine exactly as your doctor has told you. Your doctor may tell you to use a different dose of Soliqua compared to your previous insulin dose. Check with your doctor, pharmacist or nurse if you are not sure. Based on your lifestyle, your blood sugar tests and your previous insulin use, your doctor will tell you:

- How much Soliqua you need each day and at what time.
- When to check your blood sugar level and if you need to carry out urine tests.
- When you may need a higher or lower dose.

Your doctor may tell you to use Soliqua with other medicines for high blood sugar.

-How much to use

Soliqua 100 units/ml + 50 mcg/ml pre-filled pen:

- This pen provides a dose of 10 to 40 dose steps in one injection, in steps of 1 dose step.
- Each dose step you dial contains 1 unit of insulin glargine and 0.5 micrograms of lixisenatide.

Your dose of Soliqua is administered as 'dose steps'. The dose window on the pen shows the number of dose steps.

Do not inject a dose lower than 10 dose steps. Do not inject a dose higher than 40 dose steps.

If a dose greater than 40 dose steps is needed, your doctor will prescribe a different strength. For dose steps from 30-60 units, Soliqua 100 units/ml + 33 micrograms/ml solution for injection in a pre-filled pen is available.

Many factors may affect your blood sugar level. You should know what they are so that you can take the right action if your blood sugar level changes and help stop it becoming too high or too low.

Use in elderly patients (65 years and older)

If you are 65 years or older, talk to your doctor as you may need a lower dose.

If you have kidney or liver problems

If you have kidney or liver problems, talk to your doctor as you may need a lower dose.

-When to use it

Use Soliqua once a day, within 1 hour before a meal. Preferably inject Soliqua before the same meal every day, when you have chosen the most convenient way.

-How long to use it

Do not stop using this medicine without talking to your doctor. If you do, it could lead to very high blood sugar (hyperglycaemia) and a build-up of acid in the blood (ketoacidosis).

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

-If you forget to use it

If you have missed a dose of Soliqua or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycaemia):

When needed, Soliqua can be injected before the next meal.

- Do not inject a double dose to make up for a forgotten dose.

- Do not use two injections per day
- Check your blood sugar and then inject your next dose at the usual time.

-If you use too much (overdose)

If you have injected too much of this medicine, your blood sugar level may become too low (hypoglycaemia). Check your blood sugar and eat more food to prevent your blood sugar getting too low (hypoglycaemia).

While you are using it

-Things you must do

Before you inject

- Always follow the "Instructions for use" that come with this package insert.
- If you do not follow all of these instructions, you may get too much or too little of Soliqua.

To avoid mistakes, always check the medicine pack and label on the pen before each injection to make sure you have the correct pen, especially if you inject more than one medicine.

Ask your doctor or pharmacist if you are not sure.

Where to inject

Read the detailed instructions for use leaflet on where to inject.

Other important information about using the pre-filled pens

- Always use a new needle for each injection. The re-use of needles increases the risk of blocked needles which may cause under- or overdosing. Dispose of the needle safely after each use.
- Only use needles that are compatible for use with Soliqua pen (see "Instructions for Use").
- A safety test must be performed before each injection.
- If you think your pen is damaged, do not use it. Get a new one. Do not try to repair the pen.
- Throw away the used needle in a sharps container, or as told by your pharmacist or local authority.

-Things you must not do

Do not use Soliqua:

- in a vein. This will change the way it works and may cause your blood sugar to become too low.
- if there are particles in the Soliqua. The solution should be clear, colourless and water-like.

Never use a syringe to remove the solution from the pen to avoid dosing errors and potential overdose.

- To prevent infection being passed from one person to another, pens should never be used for more than one person, even when the needle is changed

-Things to be careful of

If the pen is damaged, has not been stored correctly, if you are not sure that it is working properly or you notice that your blood sugar control is unexpectedly getting worse:

- throw the pen away and use a new one.
- talk to your doctor, pharmacist or nurse if you think you have a problem with your pen.

Side Effect

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice signs of your blood sugar being too low (hypoglycaemia), take action to increase your blood sugar level straightaway.

Hypoglycaemia can be very serious and is very common with medicines containing insulin (may affect more than 1 in 10 people).

Low blood sugar means that there is not enough sugar in your blood.

If your blood sugar falls too low, you may pass out (become unconscious).

If blood sugar remains very low for too long it may cause brain damage and may be life-threatening.

Other side effects are:

Skin changes at the injection site:

If you inject Soliqua too often in the same place, the skin may either shrink (lipoatrophy) or thicken (lipohypertrophy). Also lumps under the skin caused by build-up of a protein called amyloid may occur (cutaneous amyloidosis). Frequency 'not known': Changes at the injection site (Cutaneous amyloidosis). The medicine may not work very well. Change the injection site with each injection to help prevent these changes.

Common (may affect up to 1 in 10 people)

- Feeling dizzy
- Feeling sick (Nausea)
- Vomiting
- Diarrhoea
- Skin and allergic reactions at the injection site: The signs may include

reddening, unusually intense pain when injecting, itching, hives, swelling or inflammation. This can spread around the injection site. Most minor reactions to insulins usually disappear in a few days to a few weeks.

Uncommon: may affect up to 1 in 100 people

- Cold, runny nose, sore throat
- Hives (urticaria)
- Headache
- Indigestion (dyspepsia)
- Stomachache
- Tiredness
- Gallstones
- Inflamed gallbladder
- Changed sense of taste

Rare (may affect up to 1 in 1,000 people)

- A delay in the emptying of the stomach

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Soliqua

-Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the label of the pen after "EXP". The expiry date refers to the last day of that month.

Before first use

Store in a refrigerator (2°C-8°C).

Do not freeze or place next to the freezer compartment or a freezer pack. Keep the pen in the outer carton in order to protect from light.

After first use or if carried as a spare

The pen may be stored for a maximum of 28 days out of the refrigerator, but below 25°C. Discard the pen after this period.

Do not return the pen to a refrigerator and do not freeze. Store the pen away from direct heat or direct light. Always keep the cap on the pen when you are

not using it in order to protect it from light.

Do not leave the pen in a car on an exceptionally warm or cold day.

Do not store the pen with the needle attached.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer used. These measures will help protect the environment.

Product Description

-What it looks like

Soliqua is a clear and colourless solution for injection (injection) filled in a glass cartridge inserted in a SoloStar pre-filled pen.

Each pen contains 3 ml of solution.

Packs of 3 and 5 pre-filled pens.

Not all pack sizes may be marketed.

Needles are not included in the pack.

-Ingredients:

- Active ingredients:

insulin glargine and lixisenatide. Each pen contains 300 units insulin glargine and 150 micrograms lixisenatide in 3 ml of solution. Each ml contains 100 units insulin glargine and 50 micrograms lixisenatide.

Each dose step of Soliqua contains 1 unit of insulin glargine and 0.5 micrograms of lixisenatide.

- Inactive ingredients:

85% glycerol, methionine, metacresol, zinc chloride, concentrated hydrochloric acid, and sodium hydroxide (for pH adjustment) and water for injections.

-MAL Numbers:

MAL19056044AZ

Manufacturer

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Product Registration Holder

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