

SOLIQUA®

insulin glargine + lixisenatide

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Soliqua.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Soliqua against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Soliqua is used for

Soliqua contains two active substances, insulin glargine and lixisenatide.

Soliqua is used to reduce high blood glucose (sugar) levels in people with Type 2 diabetes mellitus; it is given by injection once a day.

Soliqua is used in combination with metformin when other medicines are not enough on their own to control your blood glucose levels. These other medicines may include oral glucose-lowering medicinal products or insulin.

If you use another oral glucose-lowering medicinal product, discuss with your doctor whether you should

stop using that medicine when starting Soliqua.

Soliqua is not addictive.

Type 2 diabetes mellitus is a condition in which your pancreas does not produce enough insulin to control your blood glucose.

Ask your doctor if you have any questions about why Soliqua has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you use Soliqua

When you must not use Soliqua

Do not use Soliqua if:

- You have type 1 diabetes or diabetic ketoacidosis (often caused by high blood glucose levels)
- You are allergic to any medicine containing insulin or lixisenatide or any of the ingredients contained in Soliqua listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

If you are experiencing low blood sugar levels (hypoglycaemia-a "hypo").

If you have a lot of hypos discuss appropriate treatment with your doctor.

After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you use Soliqua after the expiry date has passed, it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.

If the product appears cloudy, discoloured or contains particles, or if the injection pen appears damaged.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not give Soliqua to a child or adolescent.

Soliqua has not been studied for use in children or adolescents under 18 years old.

Before you start to use Soliqua

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems

- a history of persistent severe abdominal pain
- pancreatitis

Tell your doctor if you have severe problems with your stomach or food digestion.

Soliqua slows stomach emptying so food passes more slowly through your stomach.

Tell your doctor if you are pregnant or plan to become pregnant.

Pregnancy may make managing your diabetes more difficult.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Tell your doctor if:

- you drink alcohol
- you do not eat regular meals
- you do a lot of exercise
- you are ill or feeling unwell

Alcohol, diet, exercise and your general health all affect your diabetes management.

If you have not told your doctor about any of the above, tell them before you start using Soliqua.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Soliqua or may affect how it works. You may need different amounts of your medicines or you may need to take your medicines at different times.

This includes:

Medicines that need to pass through the stomach quickly. Soliqua slows stomach emptying and can affect these medicines.

Medicines that may increase the blood glucose lowering effect of Soliqua including:

- glucose lowering medicinal products that are used to treat type 2 diabetes
- blood pressure, blood flow, cholesterol and heart medications
- medications for pain and inflammation
- some antidepressants
- sulfonamide antibiotics

Medicines that may reduce the blood glucose lowering effect of Soliqua including:

- corticosteroids, glucagon and other hormonal therapies
- oral contraceptives and gynaecological medications
- fluid and glaucoma medications
- tuberculosis and HIV/AIDS treatments
- some psychiatric medications
- adrenaline and asthma medications such as salbutamol, terbutaline

Certain heart medications, especially beta-blockers, may mask the symptoms of hypoglycaemia.

Some medicines may need to be taken an hour before or 11 hours after your Soliqua dose.

Your doctor and pharmacist have a full list of medicines with which you must be careful or avoid while using Soliqua. Please check with your doctor or pharmacist before starting any new medicines or over-the-counter products.

How to use Soliqua

Soliqua is a clear solution that does not require shaking before use.

Your doctor, pharmacist or diabetes educator will have shown you how to use Soliqua.

Inject into the front of your thighs, upper arms or the front of your waist (abdomen).

Change the place within the area you inject each day. This will reduce the risk of skin shrinking or thickening or lumps at the site.

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.

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 diabetes medication. Check with your doctor, pharmacist or diabetes educator if you are not sure.

Based on your lifestyle, your blood glucose 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 need a higher or lower dose.

Any change in this medicine should be made cautiously and only under medical supervision.

Read carefully the "Soliqua pen Instructions For Use" provided in the carton. You must use the pen as described in these Instructions For Use.

Do not dilute Soliqua.

Do not mix Soliqua with any other insulin or solution.

Do not inject Soliqua into a vein.

Soliqua is intended for injection under the skin.

If you do not understand the instructions, ask your doctor, pharmacist or diabetes educator for help.

MAKE SURE YOU ARE USING THE CORRECT INJECTION PEN.

Always check the label on the pen before each injection to avoid medication errors between 2 different Soliqua pens or between Soliqua and other glucose lowering medicinal products.

When to use Soliqua

Your doctor will tell you when to use Soliqua.

Soliqua should be used once a day, at the same time every day within 1 hour before the first meal each day.

How much to use

Your doctor will tell you how much Soliqua you need to use each day.

Your doctor may increase or decrease the dose, depending on your blood glucose levels.

Before you use the injector pen for the first time, your doctor or nurse will show you how to inject Soliqua.

It is very important that you manage your diabetes carefully. Too much or too little of Soliqua can cause serious effects.

Soliqua is available in two strengths

The Soliqua 100 units/mL +50 micrograms/mL pre-filled SoloStar pen:

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

The Soliqua 100 units/mL + 33 micrograms/mL pre-filled SoloStar pen:

- This pen provides a dose of 30 to 60 units in one injection, in steps of 1 unit.
- Each unit you dial contains 1 unit of insulin glargine and 0.33 micrograms of lixisenatide.

This is highlighted on the product packaging and label of the pen.

Do not use Soliqua if it is no longer clear and colourless or if it contains particles.

Keep the injection pen at room temperature for 1 or 2 hours before use. Cold medication could be more painful to inject.

Soliqua SoloStar disposable pens are pre-filled and ready to use. Once all the medicine is used you cannot replace the cartridge.

Carefully follow the instructions provided with the Soliqua SoloStar pen for attaching a needle, performing a safety test and administering the Soliqua injection.

Never use an injection pen if it is damaged or you are not sure that it is working properly. Use a new pen.

INJECTING A DOSE

Do not withdraw Soliqua from the cartridge of the pre-filled pen into a syringe.

Perform a safety check before each injection

Inject Soliqua under the skin, being careful not to inject it into a muscle or vein.

Choose a site for injection.

Inject Soliqua into the abdomen, thighs or upper arms.

1. With one hand, stabilise the skin by spreading it or pinching up a large area, as recommended by your healthcare professional.
2. Insert the needle into the skin as recommended by your healthcare professional.
3. Inject the full dose of Soliqua by pushing the plunger as far as it will go.
4. Slowly count to 10 before removing the needle from the skin.

Use a different injection site each injection so that the same site is not used more often than once a month.

This will reduce the chance of local skin reactions developing.

Refer to the instruction leaflet each time you use this medicine.

AFTER INJECTING

Using the outer needle cap, unscrew the needle and dispose of it safely into a sharps container.

Do not share needles. Do not reuse needles.

Do not attempt to replace the cartridge in a pre-filled disposable pen.

Empty disposable pens must never be reused and must be properly discarded.

How long to use Soliqua

Continue using Soliqua for as long as your doctor or pharmacist tells you.

Make sure you keep enough Soliqua to last over weekends and holidays.

HYPOGLYCAEMIA,

A "HYPO" (too low blood glucose)

If you take too much (overdose)

If you accidentally use too much Soliqua your blood glucose level may become too low (hypoglycaemia).

Immediately telephone your doctor or the Poisons Information Centre (13 11 26 in Australia; 0800 POISON or 0800 764 766 in New Zealand) if you think that you or anyone else may have used too much Soliqua.

Do this even if there are no signs of discomfort or poisoning.

The risk of hypoglycaemia is increased if you:

- accidentally use too much Soliqua

- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypoglycaemia can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

Always carry some sugary food or drink with you.

If you experience any of these symptoms of hypoglycaemia, you need to raise your blood-glucose urgently. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- 1/2 can of a sugar-containing soft drink (not a diet soft drink)
- 2-3 concentrated glucose tablets

Follow up with extra carbohydrates, e.g., plain biscuits, fruit or milk, when over the initial symptoms.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

If not treated quickly, the initial symptoms of hypoglycaemia may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and seizures.

If severe hypoglycaemia is not treated, it can cause brain damage and death.

Tell your relatives, friends, close workmates or carers that you have diabetes.

Refer to the Diabetes Australia website for more information on management of diabetes. (<https://www.diabetesaustralia.com>)

It is important that they recognise the signs and symptoms of a "hypo".

Make sure they know to turn you on your side and get medical help immediately if you lose consciousness.

Make sure they know not to give you anything to eat or drink if you are unconscious.

This is because you could choke.

Provide them with the telephone number for your doctor, the Poisons Information Centre (13 11 26 in Australia; 0800 POISON or 0800 764 766 in New Zealand) and Emergency Services.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, have some sugary food or drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes educator, or the closest hospital.

If you do not respond to glucagon treatment, you will have to be treated in a hospital.

See your doctor if you keep having "hypos" or if you have ever become unconscious after using Soliqua.

Your dose of Soliqua or other medicines may need to be changed.

HYPERGLYCEMIA (too high blood glucose)

If you miss a dose

If you forget to take your medicine, test your blood sugar level as soon as possible.

Soliqua should be taken regularly at the same time each day. If you miss taking your dose at the

regular scheduled time, your blood sugar levels may become high (hyperglycaemia).

However, taking a dose of Soliqua at another time may increase your risk of having a hypo. You should therefore plan in advance with your doctor or healthcare professional so that you know what to do in case you miss a dose.

If you have missed a dose and are not sure what you should do, contact your doctor or healthcare professional for specific advice.

Do NOT use a double dose of your medicine.

If you double a dose, this may cause low blood sugar levels.

The risk of hyperglycaemia is increased if you:

- miss doses of Soliqua or other insulin, or use less Soliqua than you need
- have fluctuating blood glucose levels
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed
- take certain other medications

High blood glucose levels over a period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood glucose level is very high or you experience any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine

- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and, in extreme cases, death if untreated.

Discuss any worries you may have about this with your doctor, pharmacist or diabetes educator.

While you are using Soliqua

Things you must do

Measure your blood sugar level regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

It is important to keep using Soliqua even if you feel well.

Soliqua helps to manage your condition but does not cure it.

Tell your doctor if you often have hypoglycaemia or if you have ever become unconscious after using Soliqua.

Your doctor may need to adjust your dose of Soliqua or of other medicines you are taking.

Always carry some sugary food or drink with you.

If you experience any of the symptoms of hypoglycaemia, immediately eat some sugary food or have a drink, e.g., jelly beans, sugar, honey, sugar-containing soft drink, glucose tablets. Diet and low calorie soft drinks do NOT contain sugar and are unsuitable to take for hypoglycaemia.

Make sure that you tell every doctor, dentist, pharmacist or other healthcare professional who is treating you that you have diabetes and are using Soliqua.

Tell your doctor, pharmacist or diabetes educator if you are travelling.

Ask your doctor for a letter explaining why you are taking injecting pens and needles with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject Soliqua and eat your meals at different times because of time differences in and between countries.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, e.g., sugar sachets or jelly beans
- carry emergency food rations in case of a delay, e.g., dried fruit, biscuits or muesli bars
- keep Soliqua readily available; take enough Soliqua for your expected needs whilst travelling - you may not be able to get Soliqua in the country you are visiting

Your doctor, pharmacist or diabetes educator can provide you with some helpful information. You may need to talk to them about

- Availability of your medicine in the country you are visiting
- Correct storage of your medicine while you are travelling
- Timing of meals and Soliqua administration while travelling
- The possible effects of changing to different time zones
- Possible new health risks in the countries to be visited
- What you should do in emergency situations when you feel unwell or become ill.

Tell your doctor if you are having trouble or difficulty with your eyesight.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

Tell your doctor, pharmacist or diabetes educator if you

Develop skin changes at the injection site. The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see How to use Soliqua). Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Things you must not do

Do not stop using Soliqua unless your doctor tells you to.

Do not skip meals while using Soliqua.

Do not use Soliqua if you think it has been frozen or exposed to excessive heat (temperatures above 25°C).

Do not give Soliqua to anyone else, even if they have the same condition as you.

Do NOT use a syringe to withdraw from the cartridge of the pre-filled pen.

Do not re-use needles

Things to be careful of

Be careful driving or operating machinery until you know how Soliqua affects you. Be careful not to let your blood glucose levels fall too low.

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia.

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your medication needs to change.

If you become sick with a cold or flu, it is very important to continue using Soliqua, even if you feel unable to eat your normal meal. If you have trouble eating solid foods, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for Soliqua. Exercise may also speed up the effect of a dose of Soliqua, especially if the exercise involves the area of the injection site (e.g., the thighs should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your Soliqua needs to change.

Side effects

Tell your doctor, pharmacist or diabetes educator as soon as possible if you do not feel well while you are using Soliqua.

Soliqua helps most people with diabetes, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, pharmacist or diabetes educator to answer any questions you may have.

The most common side effect when using Soliqua is low blood sugar levels (hypoglycaemia - a "hypo").

Tell your doctor if you notice any of the following and they worry you:

- nausea
- vomiting
- diarrhoea
- dizziness or light headedness
- redness, swelling or itching at the injection site; usually these symptoms disappear within a few weeks during continued use

Skin changes at the injection site:

If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (localised cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area.

Change the injection site with each injection to help prevent skin changes.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- disorientation
- seizures, fits or convulsions
- loss of consciousness
- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating
- drowsiness

- passing of little or no urine
- severe abdominal pain which may be accompanied by diarrhoea /and/or nausea and/or vomiting

The above list includes some very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Soliqua

Storage

All medicines should be kept where children cannot reach them.

Before use, keep unopened Soliqua pre-filled pens in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze.

Discard if frozen.

Before first use, store the pre-filled pen at room temperature for 1 to 2 hours.

Once in use, the pre-filled pen should not be put in the refrigerator and it should be kept below 25°C. Do not leave it near heat or in direct light. Discard the pre-filled pen within 28 days of first use. Pre-filled pens that have not been refrigerated, must also be discarded after 28 days.

Disposal

Dispose of used needles and disposable injection devices safely into a sharps container.

If your doctor tells you to stop using Soliqua or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Soliqua SoloStar is available in two pre-filled disposable pens; each pen contains a 3 mL cartridge of Soliqua.

Each peach coloured Soliqua (10-40) SoloStar prefilled pen contains 100 units/mL of insulin glargine and 50 micrograms/mL of lixisenatide

Each olive coloured Soliqua (30-60) SoloStar pre-filled pen contains 100 units/mL of insulin glargine and 33 micrograms/mL of lixisenatide

Soliqua is available in packs of 1, 3 and 5.

Not all pack sizes may be available.

Ingredients

Active Ingredients:

Each ml contains 100 units of insulin Glargine (100 units/mL) and 50 or 33 microgram of lixisenatide

Inactive Ingredients:

- metacresol
- methionine
- glycerol
- zinc chloride
- hydrochloric acid
- sodium hydroxide
- water for injections

Supplier

Soliqua is supplied in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

Soliqua Insulin glargine (100 units/mL) / lixisenatide
(50 microgram/ml) - AUST R
282109

Soliqua Insulin glargine (100

units/mL) / lixisenatide
(33 microgram/ml) - AUST R
282401

This leaflet was prepared in
November 2020

Further information

You can get more information about diabetes and insulin from:

- Diabetes Australia:
freecall helpline 1300 136 588
www.diabetesaustralia.com.au
- Diabetes NZ:
freecall helpline: 0800 369 636
www.diabetes.org.nz

soliqua-ccds2-cmiv2-16nov20