**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S3

**SOLIQUA 33/100, 33 µg/mL and 100 units/mL, solution for injection**

**SOLIQUA 50/100, 50 µg/mL and 100 units/mL, solution for injection**

**Lixisenatide/Insulin glargine**

**Sugar free**

**Read all of this leaflet carefully before you start using SOLIQUA**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SOLIQUA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- Read the INSTRUCTIONS FOR USE (10 – 40 pen) and the INSTRUCTIONS FOR USE (30 – 60 pen) information before using SOLIQUA.

**What is in this leaflet**

1. What SOLIQUA is and what it is used for

2. What you need to know before you use SOLIQUA

3. How to use SOLIQUA

4. Possible side effects

5. How to store SOLIQUA

6. Contents of the pack and other information.

## 1. What SOLIQUA is and what it is used for

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.

SOLIQUA is used to treat adults with type 2 diabetes, to help control blood sugar levels when they are too high. It is given with other antidiabetic medicines when the other medicines are not enough on their own to control your blood sugar levels. These other medicines may include oral anti-diabetics (such as metformin, sulfonylurea medicines) or insulin.

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

## 2. What you need to know before you use SOLIQUA

**Do not use SOLIQUA:**

- if you are hypersensitive (allergic) to insulin glargine, lixisenatide or any of the other

ingredients of SOLIQUA (listed in section 6)

- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- if you are experiencing episodes of hypoglycaemia (see *Hypoglycaemia*)
- if you have sudden inflammation of your pancreas including symptoms such as severe stomach pain, fever, rapid pulse, nausea and vomiting
- if you have severe kidney problems or kidney disease
- if you have type 1 diabetes, as SOLIQUA is used for type 2 diabetes and this medicine will not be right for you
- if 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
- if 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 (see Other medicines and SOLIQUA)
- if you are on dialysis as the use of this medicine will not be recommended.

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

**Warnings and precautions**

**Special care should be taken with SOLIQUA:**

- Too low blood sugar (hypoglycaemia). If your blood sugar is too low, follow the guidance for

hypoglycaemia (see *Hypoglycaemia*).

- Too high blood sugar (hyperglycaemia). If your blood sugar is too high, follow the guidance for hyperglycaemia (see *Hyperglycaemia*).
- Ensure that you use the right medicine. You must always check the label before each injection to avoid mix-ups between SOLIQUA and other insulins.

While using this medicine be aware of the following and talk to your doctor, pharmacist or other health care provider before using SOLIQUA:

- Severe pain in your stomach area (abdomen) that will not go away. This could be a sign of inflamed pancreas (acute pancreatitis). Also, tell your doctor if you have a history of pancreatitis.
- Loss of fluid from your body (dehydration), e.g. in case of vomiting and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids, especially during the first weeks of treatment with SOLIQUA.
- 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 medicine dose.
- Gallbladder inflammation or gallstones have been seen in people who took medicines belonging to the same family of antidiabetic medicines as lixisenatide as in SOLIQUA. If you have stomach pain, fever, nausea or yellowing of the skin and eyes, talk to your doctor.

*Travel:*

Talk to your doctor before travelling. You may need to talk about:

- if your medicine is available in the country, you are visiting
- how to arrange the supply of your medicine, needles and other items
- how to correctly store your medicine while travelling
- the time you eat meals and use your medicine
- the possible effects of changing to different time zones
- any health risks in the countries you will visit
- what you should do in an emergency if you feel unwell or become ill.

**Children and adolescents**

SOLIQUA is not for use in children and adolescents below 18 years of age.

**Other medicines and SOLIQUA**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines can change your blood sugar level. This may mean your SOLIQUA dose has to change. So, before taking a medicine ask your doctor if it will affect your blood sugar and what action, if any, you need to take.

The effect of some medicines you swallow might be affected by SOLIQUA. Some medicines such as antibiotics, oral contraceptives, statins (medicines like atorvastatin to lower cholesterol),

acid-resistant tablets or capsules that should not stay too long in your stomach, may need to be taken at least one hour before or eleven hours after your SOLIQUA injection.

*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 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 infection
- 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 adrenaline (epinephrine), 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, 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 (medicine 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 food and drink**

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

**Pregnancy and breastfeeding**

SOLIQUA should not be used during pregnancy.

SOLIQUA should not be used if breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking SOLIQUA.

**Driving and using machines**

SOLIQUA has no or negligible influence on the ability to drive a vehicle or use machines.

Having too low or too high blood sugar (see HYPERGLYCAEMIA AND HYPOGLYCAEMIA) 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.

**SOLIQUA contains metacresol and sodium**

SOLIQUA contains metacresol which may cause allergic reactions.

SOLIQUA contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially sodium free.

## 3. How to use SOLIQUA

Do not share medicines prescribed for you with any person.

Always use SOLIQUA exactly as your doctor has told you. You should check with your doctor or pharmacist 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.

### How much to use

SOLIQUA comes in two pen strengths:

SOLIQUA 50/100 pre-filled pen, the 10 – 40 dose pen (olive-coloured 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 0,5 micrograms of lixisenatide and 1 unit of insulin glargine
- this pen is for the daily injection of 10 to 40 dose steps of SOLIQUA.

Your dose of SOLIQUA is administered as ‘dose steps’. The dose window on the pen shows the number of dose steps. For dose steps from 30 – 60 units, SOLIQUA 33/100 solution for injection

in a pre-filled pen is available (SOLIQUA 30 – 60 pen).

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.

SOLIQUA 33/100 pre-filled pen, the 30 – 60 dose pen (peach-coloured pen):

- this pen provides a dose of 30 to 60 dose steps in one injection, in steps of 1 dose step
- each dose step you dial contains 0,33 micrograms of lixisenatide and 1 unit of insulin glargine
- this pen is for the daily injection of 30 to 60 dose steps of SOLIQUA.

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 30 dose steps. If a dose lower than 30 dose steps is needed, use the SOLIQUA 50/100 pre-filled pen (SOLIQUA 10 – 40 pen).

Do not inject a dose greater than 60 dose steps.

**To avoid medicine errors, make sure the correct SOLIQUA pen (10 – 40 pen or 30 – 60 pen), is stated on the prescription.**

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 inject SOLIQUA**

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 time.

**Before injecting SOLIQUA**

- 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 if you are not sure.

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.

- 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.
- Only use needles that are compatible 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.

**How to inject**

- SOLIQUA is injected under the skin (subcutaneous use or “SC”)
- Inject it 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 developing dents 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.

**Do not use SOLIQUA**

- **Do not use 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.

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 is unexpectedly getting worse:

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

If you have the impression that the effect of SOLIQUA is too strong or too weak, tell your doctor or pharmacist.

**If you use more SOLIQUA than you should**

If you have injected too much of SOLIQUA, 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). If your blood sugar gets too low, see '*Hypoglycaemia'* for advice.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to use SOLIQUA**

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 use a double dose to make up for **f**orgotten individual doses
- do not use two injections per day
- check your blood sugar and then inject your next dose at the usual time
- for information on the treatment of hyperglycaemia, see '*Hyperglycaemia'*.

**If you stop using SOLIQUA**

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

## 4. Possible side effects

SOLIQUA can have side effects.

Not all side effects reported for SOLIQUA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SOLIQUA, please consult your health care provider for advice.

If any of the following happens, stop using SOLIQUA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SOLIQUA. You may need urgent medical attention or hospitalisation.

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

Take careful note of the information on hyperglycaemia and hypoglycaemia found at the end of this information leaflet.

**Other side effects**

Tell your doctor if you notice any of the following:

*Frequent:*

- feeling dizzy
- feeling sick (nausea)
- vomiting
- diarrhoea.

*Less frequent:*

- cold, runny nose, sore throat

- hives (urticaria)
- headache
- indigestion (dyspepsia)
- stomach ache
- tiredness
- changes where the injection is given: if you injection SOLIQUA too often in the same place, you may develop dents at the site, caused by a loss of fat under the skin (lipoatrophy) or you may develop lumps, caused by a build-up of fat under the skin (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (localised cutaneous amyloidosis). SOLIQUA may not work very well. Change the injection site with each injection to help prevent these changes
- 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.
- A delay in the emptying of the stomach.

*Unknown frequency:*

- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects:**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SOLIQUA.
Side effects can be reported directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

## 5. How to store SOLIQUA

Store all medicines out of 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 the month.

**Before first use**

Store between 2 °C – 8 °C (in refrigerator).

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 at or 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 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.

Do not use if you notice visible particles.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What SOLIQUA contains

The active substances are lixisenatide and insulin glargine.

SOLIQUA 33/100 contains 33 µg lixisenatide and 100 units insulin glargine.

SOLIQUA 50/100 contains 50 µg lixisenatide and 100 units insulin glargine.

The other ingredients are concentrated hydrochloric acid (for pH adjustment), glycerol (85 %), metacresol, methionine, sodium hydroxide (for pH adjustment), water for injection and zinc chloride.

### What SOLIQUA looks like and contents of the pack

SOLIQUA is available as sterile, clear and colourless solution for injection. The solution should not have any visible particles.

The SOLIQUA 33/100 disposable pen contains a 3 mL type I, clear and colourless glass

cartridge closed with an aluminium flanged cap with punched isoprene rubber, grey laminated sealing disk and a black bromobutyl rubber plunger stopper, and filled with the SOLIQUA solution for injection. It is olive-coloured with a brown injection button.

The SOLIQUA 50/100 disposable pen contains a 3 mL type I, clear and colourless glass cartridge closed with an aluminium flanged cap with punched isoprene rubber, grey laminated sealing disk and a black bromobutyl rubber plunger stopper, and filled with the SOLIQUA solution for injection. It is peach-coloured with an orange injection button.

Each pen contains 3 mL solution.

The pen-injector is a disposable device combined with a cartridge that is used to dispense variable doses of SOLIQUA. The design of the pen-injector is based on the already marketed SoloStar® pen-injector, with modifications comprising of the colour of the bodies, caps, injection buttons, and dose selectors as well as the scale on the number sleeves and the dose stop for the maximum dispensable doses.

Packs of 1, 3 or 5 pre-filled pens.

Needles are not included in the pack.

Not all pack sizes may be marketed.

**Holder of certificate of registration**

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**Registration numbers**

SOLIQUA 33/100: 52/32.16/0149 (Master)

SOLIQUA 50/100: 52/32.16/0150 (Master)

**HYPERGLYCAEMIA AND HYPOGLYCAEMIA**

**If you use insulin, you should always carry the following things with you:**

- foods containing sugar, such as dextrose tablets or a sugary drink (at least 20 grams)
- information so that others know you have diabetes.

*Hyperglycaemia (high blood sugar levels)*

**If your blood sugar is too high (hyperglycaemia), you may not have injected enough insulin.**

Reasons why hyperglycaemia may happen – examples include:

- you have not injected your SOLIQUA or not injected enough
- your medicine has become less effective – for example because it was not stored properly
- your pen does not work properly
- you are doing less exercise than usual
- you are under stress – such as emotional distress or excitement
- you have an injury, infection or fever or have had an operation
- you are taking or have taken certain other medicines (see Taking other medicines with SOLIQUA).

**Warning signs of hyperglycaemia**

Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heartbeat, and urine test showing glucose and ketone bodies. Stomach pain, fast and deep breathing, feeling sleepy or passing out (becoming unconscious) may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

**What to do if you experience hyperglycaemia**

- test your blood sugar level and, if it is high, as agreed with your doctor or nurse, test your urine for ketones as soon as you notice any of the above signs

- contact your doctor straight away if you have severe hyperglycaemia or ketoacidosis. This must always be treated by a doctor, normally in a hospital.

***Hypoglycaemia (low blood sugar levels)***

If your blood sugar level falls too much you may pass out (become unconscious). Serious hypoglycaemia may cause a heart attack or brain damage and may be life-threatening. You should learn to recognise the signs when your blood sugar is falling, so you can take action to stop it getting worse.

**Reasons why hypoglycaemia may happen**

Examples include:

- you inject too much SOLIQUA
- you miss meals or delay them
- you do not eat enough, or eat food containing less carbohydrates than normal. Artificial sweeteners are not carbohydrates
- you drink alcohol, especially when you have not eaten much
- you lose carbohydrates from being sick (vomiting) or diarrhoea
- you are doing more exercise than usual or a different type of physical activity
- you are recovering from an injury, operation or other stress
- you are recovering from an illness or from fever
- you are taking or have stopped taking certain other medicines (see Taking other medicines with SOLIQUA).

**Hypoglycaemia is also more likely to happen if**

- you have just started SOLIQUA treatment. If low blood sugar occurs, it may be more likely to happen in the morning
- your blood sugar levels are almost normal or are unstable
- you change the area where you inject SOLIQUA, for example, from the thigh to the upper arm
- you have severe kidney or liver disease, or some other disease such as hypothyroidism.

**Warning signs of hypoglycaemia**

The first signs may be in your body generally. Examples of signs that your blood sugar level is falling too much or too fast include: sweating, clammy skin, feeling anxious, fast or irregular heartbeat, high blood pressure and palpitations. These signs often develop before the signs of a low sugar level in the brain.

Other signs include: headaches, feeling very hungry, feeling sick (nausea) or being sick (vomiting), feeling tired, sleepy, restless, sleeping problems, aggressive behaviour, difficulty concentrating, slow reactions, depression, feeling confused, difficulty speaking (sometimes total loss of speech), changes in your sight, trembling, being unable to move (paralysis), tingling in the hands or arms, feeling numb and tingling often around the mouth, feeling dizzy, loss of self-control, being unable to look after yourself, fits, passing out.

**When these signs of hypoglycaemia may be less clear**

The first warning signs of hypoglycaemia may change, be weaker or missing altogether if:

- you are elderly
- you have had diabetes for a long time
- you have a certain type of nerve damage (called diabetic autonomic neuropathy)
- you have recently had too low blood sugar (for example the day before)
- your low blood sugar comes on slowly
- your low blood sugar is always around “normal”, or your diabetes control has greatly improved recently
- you have recently changed from animal insulin to a manufactured insulin, like there is in SOLIQUA
- you are taking or have taken certain other medicines (see Taking other medicines with SOLIQUA).

In such cases, you may develop severe hypoglycaemia (and even pass out) before you know what is happening. Be familiar with your warning signs. If necessary, you might need to test your blood sugar more often. This can help to spot mild hypoglycaemic episodes. If you find it difficult to recognise your warning signs, you should avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

**What to do if you experience hypoglycaemia**

1. Do not inject SOLIQUA. Take about 15 to 20 grams sugar straight away, such as glucose, sugar cubes or a sugary drink. Drink or foods that contain artificial sweeteners (such as diet drinks) do not help treat low blood sugar.
2. You might then need to eat something (such as bread or pasta) that will raise your blood sugar over a longer time, especially if your next meal is not due. Ask your doctor or nurse if you are not sure which foods you should eat. With SOLIQUA, it may take longer to

recover from low blood sugar because it contains a long-acting insulin (insulin glargine).

3. Test your blood glucose levels after 10 – 15 minutes after taking sugar. If blood glucose levels are still too low (< 4 mmol/L) or hypoglycaemia comes back, take another 15 to 20 grams of sugar.
4. Speak to a doctor straightaway if you are not able to control the hypoglycaemia, or it comes back again.

**What other people should do if you have hypoglycaemia**

Tell your relatives, friends and close colleagues to get medical help straightaway if you are not able to swallow or if you pass out (become unconscious).

You will require an injection of glucose or glucagon (a medicine which increases blood sugar). These injections should be given even if it is not certain that you have hypoglycaemia.

You should test your blood sugar straightaway after taking glucose to check that you really have hypoglycaemia.

**INSTRUCTIONS FOR USE (10 – 40 pen)**

SOLIQUA (10 – 40) pen contains insulin glargine and lixisenatide. The combination of medicines in this pen is for the daily injection of 10 to 40 dose steps of SOLIQUA.

- **Never re-use needles.** If you do, you might not get your full dose (underdosing) or get too much (overdosing) as the needle could block.
- **Never use a syringe to remove medicine from your pen.** If you do, you may not get the correct amount of medicine.

Keep these INSTRUCTIONS FOR USE for future reference.

**Important information**

- Never share your pen.  It is only for you.
- Never use your pen if it is damaged or if you are not sure that it is working properly.
- Always perform a safety test.  See **STEP 3**.
- Always carry a spare pen and spare needles in case they get lost or stop working.
- Always check the label of the pen before use to make sure you have the correct pen.

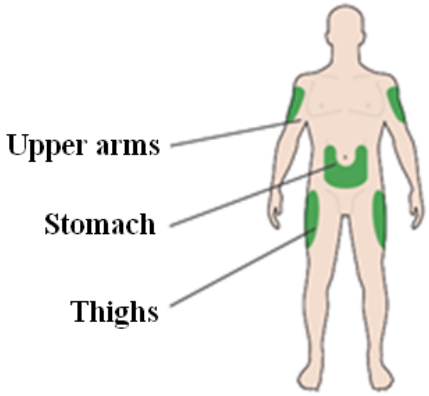
**Learn to inject**

- Talk with your doctor about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems with your sight
- Read all of these instructions before using your pen.  If you do not follow all of these instructions, you may get too much or too little medicine.

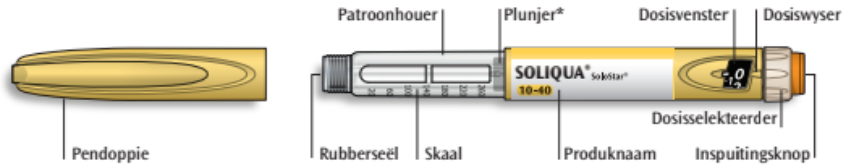
**Extra items you will need**

- A new sterile needle (see **STEP 2**).
- A sharps container for used needles and pens (see **Throwing your pen away**).

**Places to inject**




**Get to know your pen**




* Jy sal nie die plunjer sien totdat jy 'n paar dosisse ingespuit het nie

**STEP 1: Check your pen**

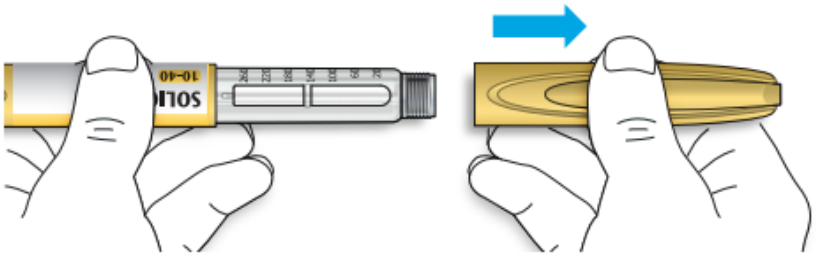
Take a new pen out of the refrigerator at least **1 hour** before you inject. Injecting cold medication is more painful.

**A. Check the name and expiry date on the label of your pen:**

- Make sure you have the correct medicine. This pen is peach-coloured with an orange injection button.
- **Do not use this pen if you need a daily dose less than 10 dose steps or if you need more than 40 dose steps. Discuss with your doctor which pen is suitable for your needs.**
- **Do not** use your pen after the expiry date.

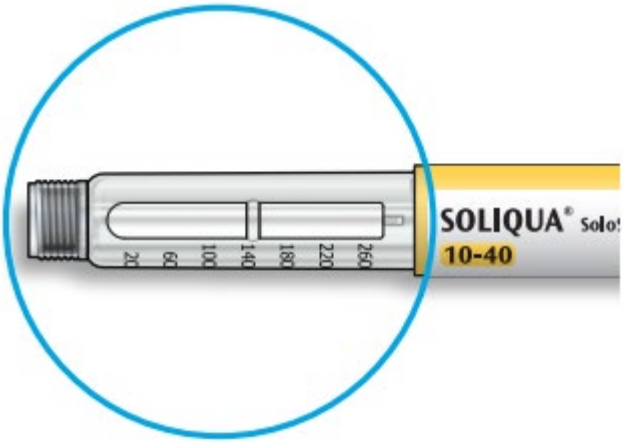



**B. Pull off the pen cap.**



**C. Check that the medicine is clear.**

- **Do not** use the pen if the medicine looks cloudy, coloured or contains particles.



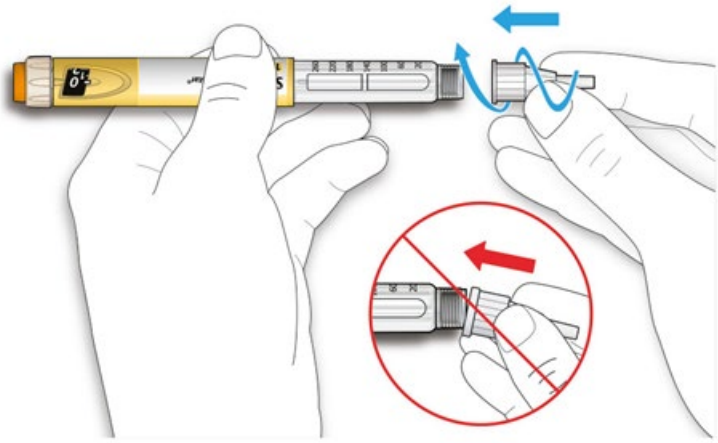

**STEP 2: Attach a new needle**

- **Do not** reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection.
- Always use needles that are compatible for use with SOLIQUA pen.

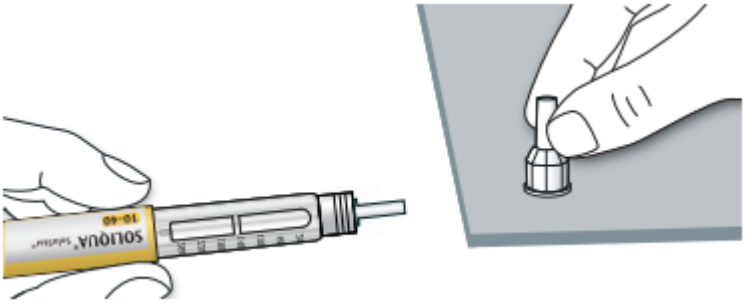
**A. Take a new needle and peel off the protective seal.**



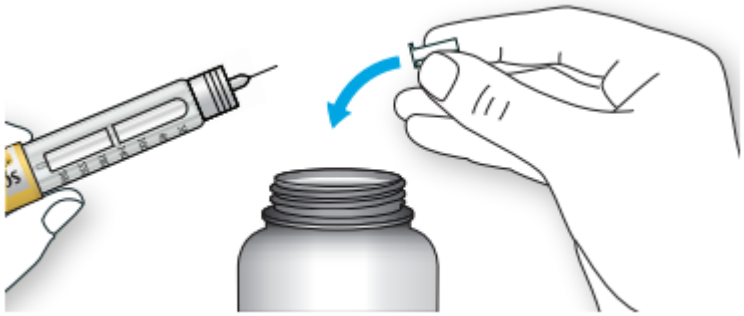
**B. Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.**



**C. Pull off the outer needle cap. Keep this for later.**



**D. Pull off the inner needle cap and throw away.**



**Handling needles**

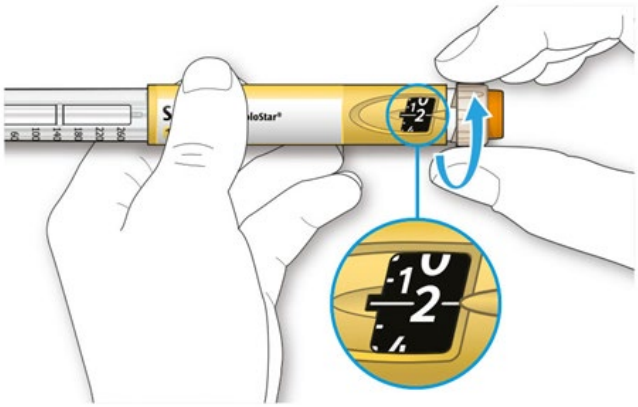
- Take care when handling needles to prevent needle injury and cross-infection.

**STEP 3: Do a safety test**

Always do a safety test before each injection to:

- Check your pen and the needle to make sure they are working properly.
- Make sure that you get the correct dose.

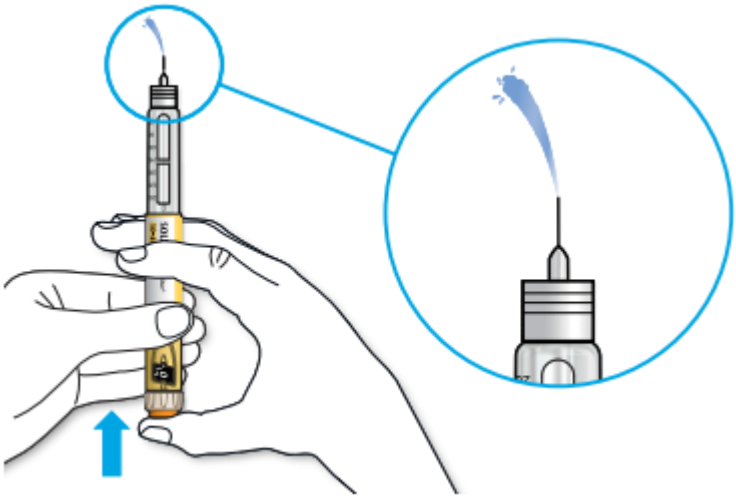
**A. Select 2 dose steps by turning the dose selector until the dose pointer is at the 2 mark.**



**B. Press the injection button all the way in.**

**a.** When medicine comes out of the needle tip, your pen is working correctly. The dose

selector will reset to “0”.



**If no liquid appears**

- You may need to repeat this step up to 3 times before seeing medicine.
- If no medicine comes out after the third time, the needle may be blocked. If this happens:
  - change the needle (see **STEP 6** and **STEP 2**)
  - then repeat the safety test (**STEP 3**)
- **Do not** use your pen if there is still no medicine coming out of the needle tip. Use a new pen.
- Do not use a syringe to remove medicine from your pen.

**If you see air bubbles**

- You may see air bubbles in the medicine. This is normal, they will not harm you.

**STEP 4: Select the dose**

- **Use this pen only to inject single daily doses from 10 to 40 dose steps.**
- **Do not** select a dose or press the injection button without a needle attached. This may

damage your pen.

**A. Make sure a needle is attached and the dose is set to ”0”.**

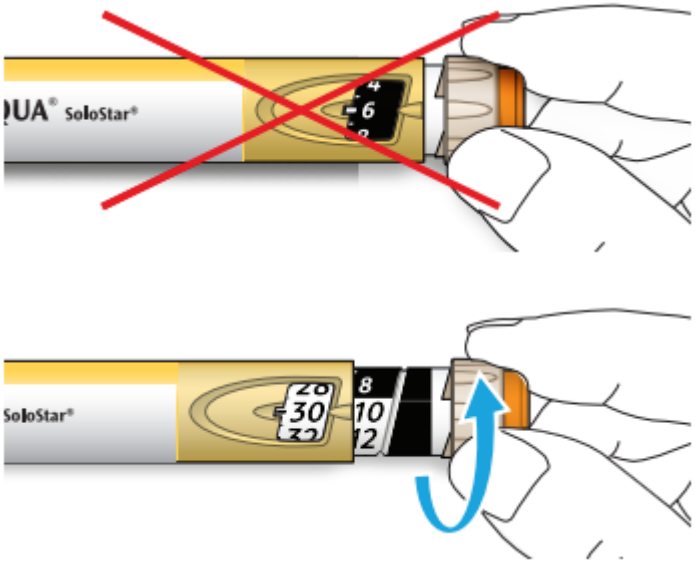



**B. Turn the dose selector until the dose pointer lines up with your dose.**

- If you turn past your dose, you can turn back down.
- If there are not enough dose steps left in your pen for your dose, the dose selector will stop at the number of dose steps left.
- If you cannot select your full prescribed dose, use a new pen or inject the remaining dose steps and use a new pen to complete your dose. Only in this case, it is okay to inject a partial dose of less than 10 dose steps. Always use another SOLIQUA (10 – 40) pen to complete your dose and no other pen.

**How to read the dose window**

- Do not use the pen if your single daily dose is less than 10 dose steps, shown as white numbers on a black background.



**Units of medicine in your pen**

- Your pen contains a total of 300 dose steps. You can select your dose in steps of 1 dose step.
- **Do not** use this pen if you need a single daily dose that is less than 10 dose steps, or more than 40 dose steps.
- Each pen contains more than 1 dose.

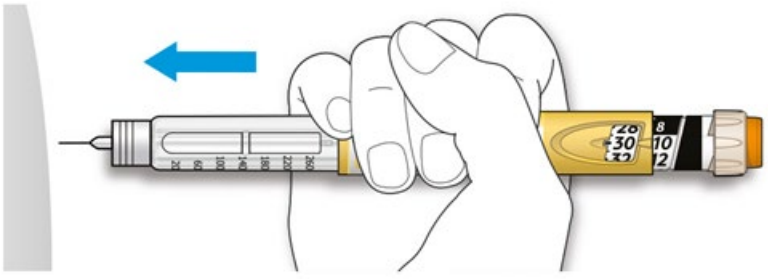
**STEP 5: Inject the dose**

- If you find it hard to press the injection button in, do not force it as this may break your pen.
  - change the needle (see **STEP 6** and **STEP 2**) then do a safety test (see **STEP 3**)
  - if you still find it hard to press in, get a new pen
  - do not use a syringe to remove medicine from your pen.

**A. Choose a place to injection as shown in the picture above.**

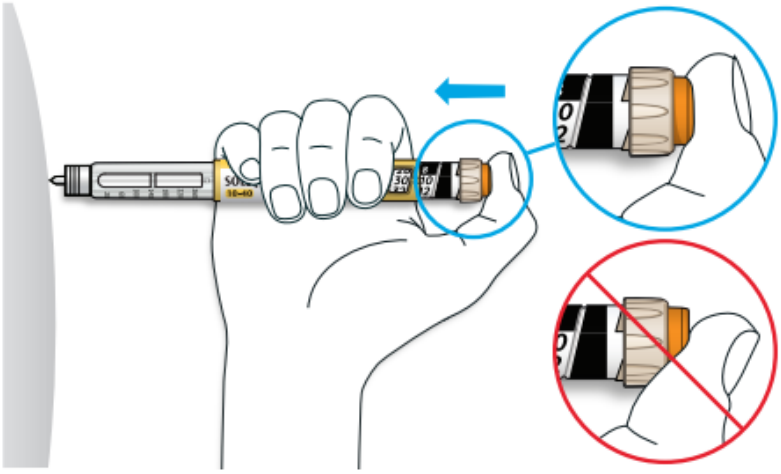
**B. Push the needle into your skin as shown by your doctor.**

- Do not touch the injection button yet.



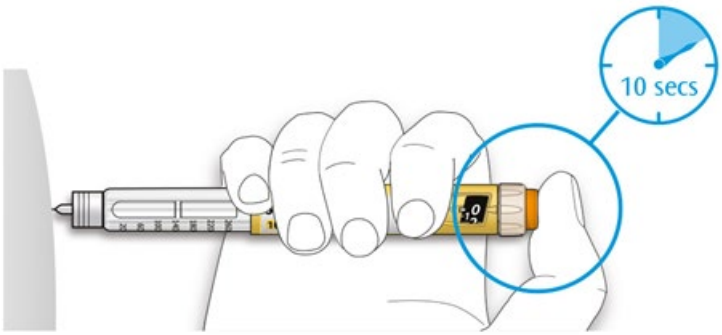
**C. Place your thumb on the injection button. Then press all the way in and hold.**

- Do not press at an angle. Your thumb could block the dose selector from turning.



**D. Keep the injection button held in and when you see ”0” in the dose window, slowly count to 10.**

- This will make sure you get your full dose.



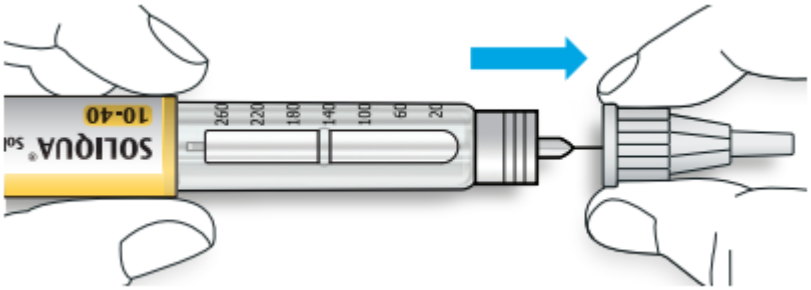

**E. After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.**

**STEP 6: Remove the needle**

- Take care when handling needles to prevent needle injury and cross-infection.
- Do not put the inner needle cap back on.

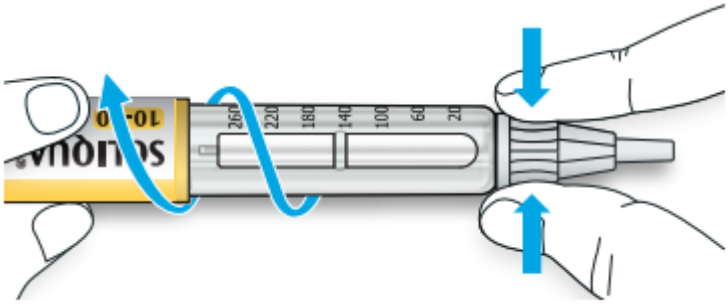
**A. Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back. Then push firmly on.**

- The needle can puncture the cap if it is recapped at an angle.

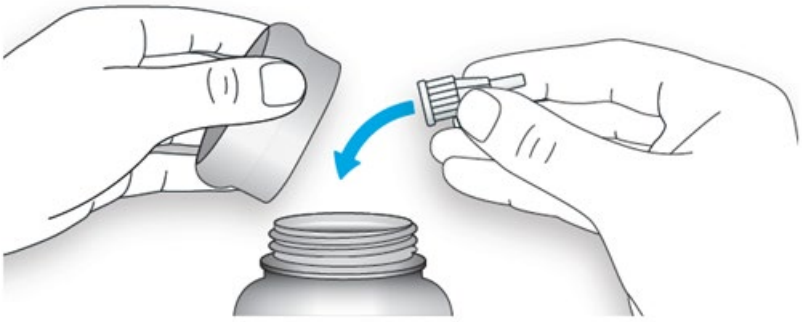



**B. Grip and squeeze the widest part of the outer needle cap.** Turn your pen several times with your other hand to remove the needle.

- Try again if the needle does not come of the first time.

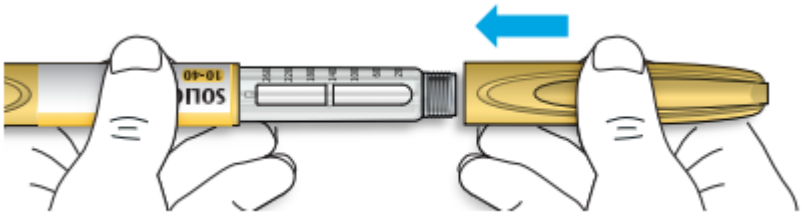


**C. Throw away the used needle in a puncture resistant container** (see **Throwing your pen away**).



**D. Put your pen cap back on.**

- Do not put the pen back in the refrigerator.



**How to store your pen**

**Before first use:**

- Keep new pens in the refrigerator between 2 °C – 8 °C.
- **Do not** freeze.

**After first use**:

- Keep your pen at room temperature, at or below 25 °C.
- **Do not** put your pen back in the refrigerator.
- **Do not** store your pen with the needle attached.
- Store the pen with your pen cap on.
- Only use your pen for up to 28 days after its first use.

**How to care for your pen**

**Handle your pen with care**

- I you think that your pen may be damaged, do not try to fix it. Use a new one.

**Protect your pen from dust and dirt**

- You can clean the outside of your pen by wiping it with a damp cloth (water only). **Do not** soak, wash or lubricate the pen. This may damage it.

**Throwing your pen away**

- Remove the needle before throwing your pen away.
- Throw away your used pen as instructed by your pharmacist.

**INSTRUCTIONS FOR USE (30 – 60 pen)**

SOLIQUA (30 – 60) pen contains insulin glargine and lixisenatide. The combination of medicines in this pen is for the daily injection of 30 to 60 dose steps of SOLIQUA.

- **Never re-use needles.** If you do, you might not get your full dose (underdosing) or get too much (overdosing) as the needle could block.
- **Never use a syringe to remove medicine from your pen.** If you do, you may not get the correct amount of medicine.

Keep these INSTRUCTIONS FOR USE for future reference.

**Important information**

- Never share your pen. It is only for you.
- Never use your pen if it is damaged or if you are not sure that it is working properly.
- Always perform a safety test. See **STEP 3**.
- Always carry a spare pen and spare needles in case they get lost or stop working.
- Always check the label of the pen before use to make sure you have the correct pen.

**Learn to inject**

- Talk with your doctor about how to inject, before using your pen.
- Ask for help if you have problems handling the pen, for example if you have problems

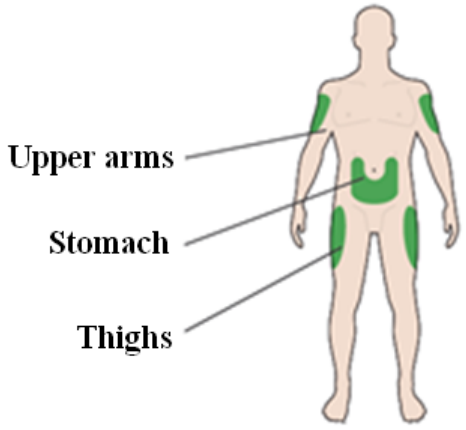
with your sight.

- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little medicine.

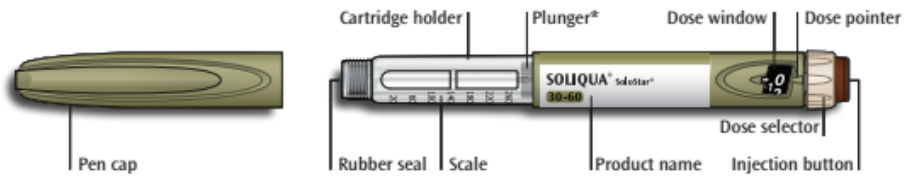
**Extra items you will need**

- A new sterile needle (see **STEP 2**).
- A sharps container for used needles and pens (see **Throwing your pen away**).

**Places to inject**




**Get to know your pen**




* You will not see the plunger until you have injected a few doses

**STEP 1: Check your pen**

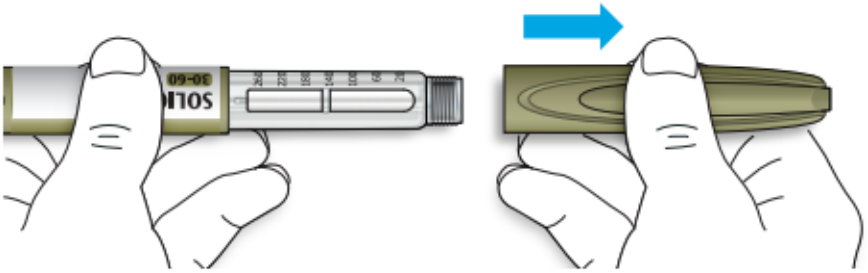
Take a new pen out of the refrigerator at least **1 hour** before you inject. Injecting cold medication is more painful.

**A. Check the name and expiry date on the label of your pen:**

- Make sure you have the correct medicine. This pen is olive-coloured with a brown injection button.
- **Do not use this pen if you need a daily dose less than 30 dose steps or if you need more than 60 dose steps. Discuss with your doctor which pen is suitable for your needs**.
- **Do not** use your pen after the expiry date.

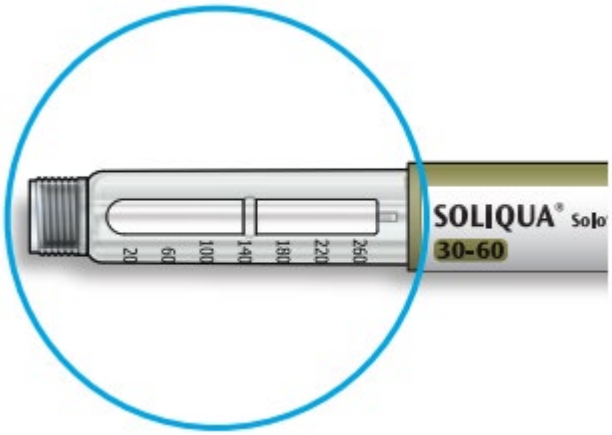



**B. Pull off the pen cap.**



**C. Check that the medicine is clear.**

- **Do not** use the pen if the medicine looks cloudy, coloured or contains particles.



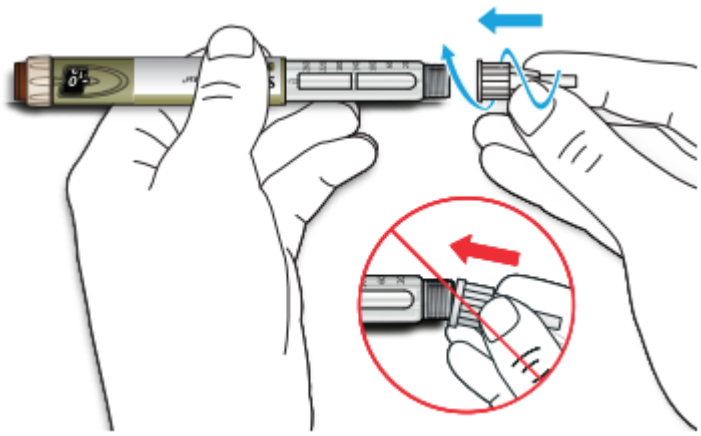

**STEP 2: Attach a new needle**

- **Do not** reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection.
- Always use needles that are compatible for use with SOLIQUA pen.

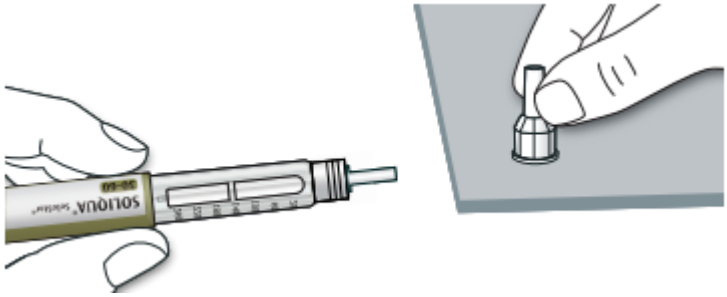
**A. Take a new needle and peel off the protective seal.**



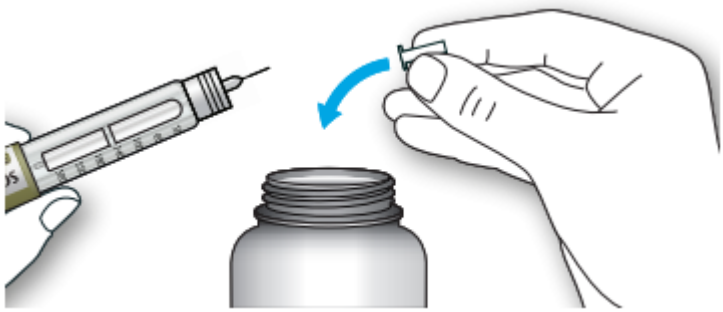
**B. Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.**



**C. Pull off the outer needle cap. Keep this for later.**



**D. Pull off the inner needle cap and throw away.**



**Handling needles**

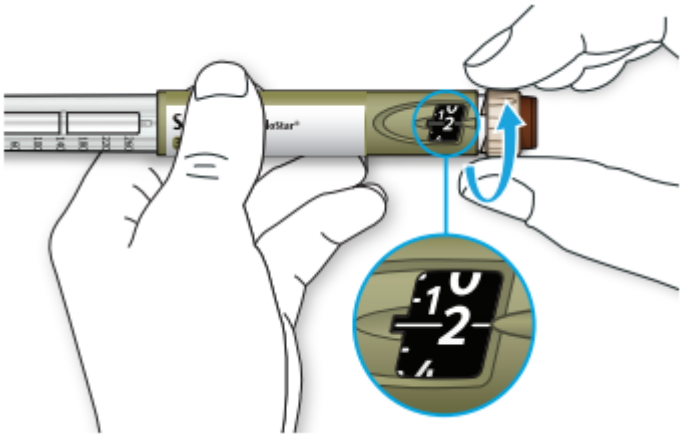
- Take care when handling needles to prevent needle injury and cross-infection.

**STEP 3: Do a safety test**

Always do a safety test before each injection to:

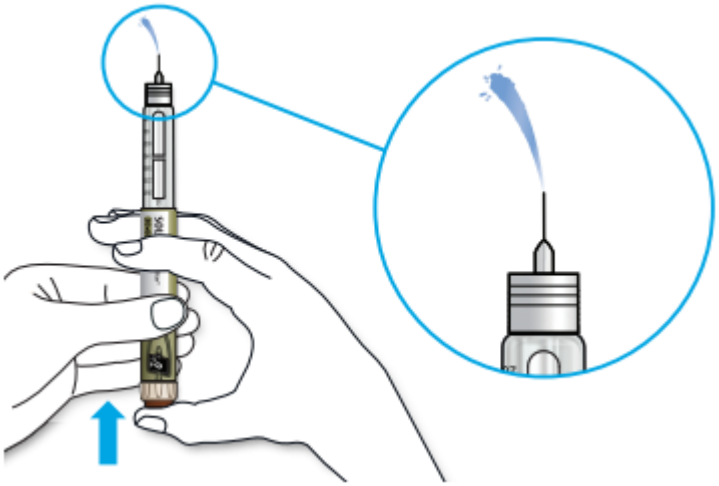
- Check your pen and the needle to make sure they are working properly.
- Make sure that you get the correct dose.

**A. Select 2 dose steps by turning the dose selector until the dose pointer is at the 2 mark.**



**B. Press the injection button all the way in.**

- When medicine comes out of the needle tip, your pen is working correctly. The dose selector will reset to “0”.



**If no liquid appears**

- You may need to repeat this step up to 3 times before seeing medicine.
- If no medicine comes out after the third time, the needle may be blocked. If this happens:

- change the needle (see **STEP 6** and **STEP 2**)
- then repeat the safety test (**STEP 3**)

- **Do not** use your pen if there is still no medicine coming out of the needle tip. Use a new pen.
- Do not use a syringe to remove medicine from your pen.

**If you see air bubbles**

- You may see air bubbles in the medicine. This is normal, they will not harm you.

**STEP 4: Select the dose**

- **Use this pen only to inject single daily doses from 30 to 60 dose steps**.
- **Do not** select a dose or press the injection button without a needle attached. This may damage your pen.

**A. Make sure a needle is attached and the dose is set to "0".**

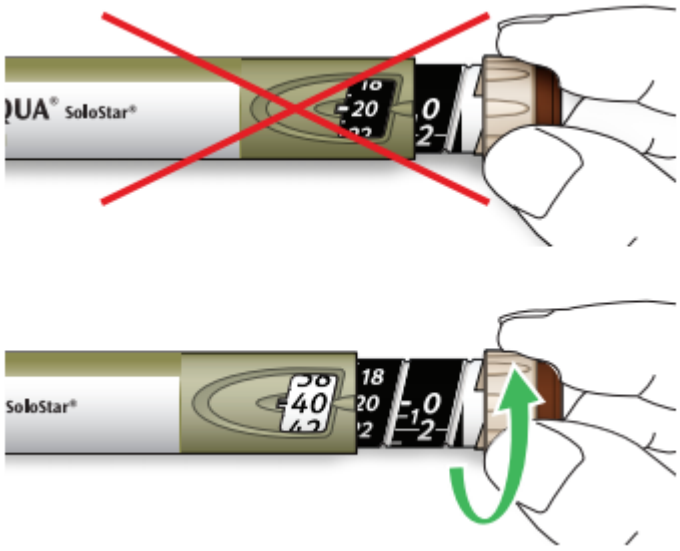



**B. Turn the dose selector until the dose pointer lines up with your dose.**

- If you turn past your dose, you can turn back down.
- If there are not enough dose steps left in your pen for your dose, the dose selector will stop at the number of dose steps left.
- If you cannot select your full prescribed dose, use a new pen or inject the remaining dose steps and use a new pen to complete your dose. Only in this case, it is okay to inject a partial dose of less than 10 dose steps. Always use another SOLIQUA (30 – 60) pen to complete your dose and no other pen.

**How to read the dose window**

- Do not use the pen if your single daily dose is less than 30 dose steps, shown as white numbers on a black background.




**Units of medicine in your pen**

- Your pen contains a total of 300 dose steps. You can select your dose in steps of 1 dose step.
- **Do not** use this pen if you need a single daily dose that is less than 30 dose steps, or more than 60 dose steps.
- Each pen contains more than 1 dose.

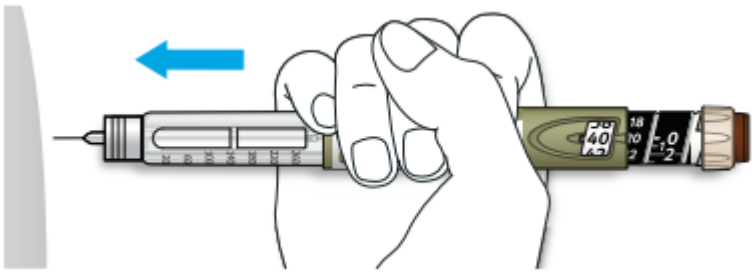
**STEP 5: Inject the dose**

- If you find it hard to press the injection button in, do not force it as this may break your pen.
  - change the needle (see **STEP 6** and **STEP 2**) then do a safety test (see **STEP 3**)
  - if you still find it hard to press in, get a new pen
  - do not use a syringe to remove medicine from your pen.

**A. Choose a place to injection as shown in the picture above.**

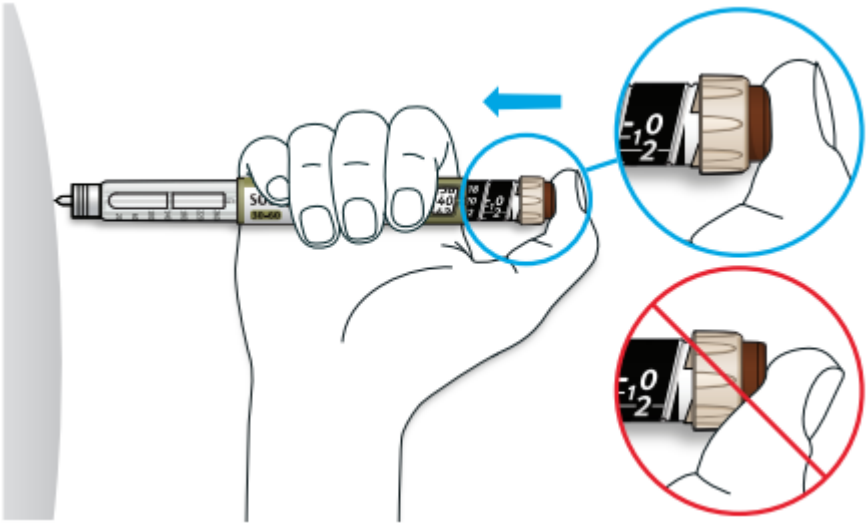
**B. Push the needle into your skin as shown by your doctor.**

- Do not touch the injection button yet.



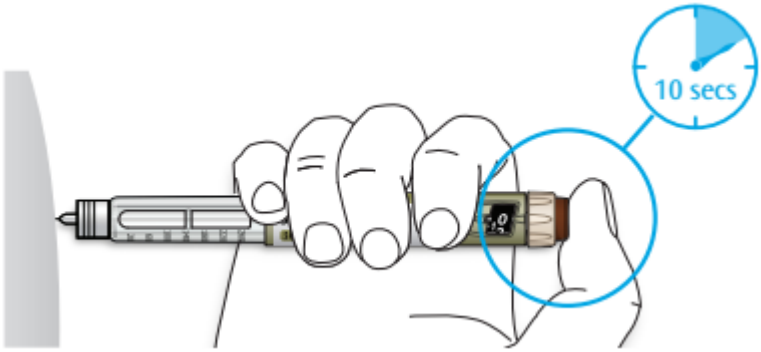
**C. Place your thumb on the injection button. Then press all the way in and hold.**

- Do not press at an angle. Your thumb could block the dose selector from turning.



**D. Keep the injection button held in and when you see ”0” in the dose window, slowly count to 10.**

- This will make sure you get your full dose.



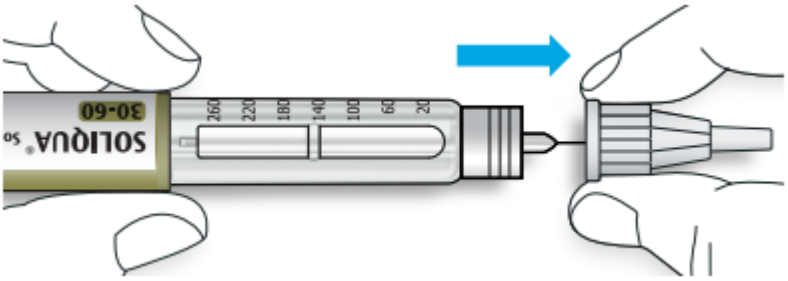
E. **After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.**

**STEP 6: Remove the needle**

- Take care when handling needles to prevent needle injury and cross-infection.
- Do not put the inner needle cap back on.

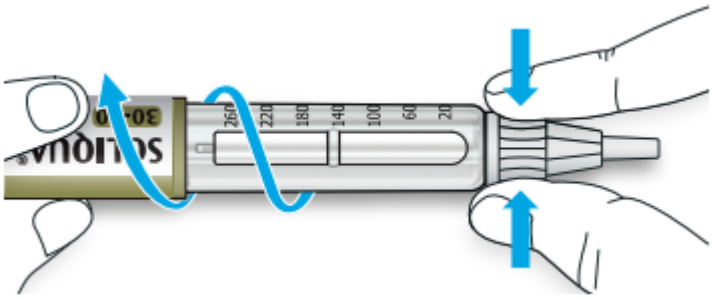
A. **Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back. Then push firmly on.**

    - The needle can puncture the cap if it is recapped at an angle.

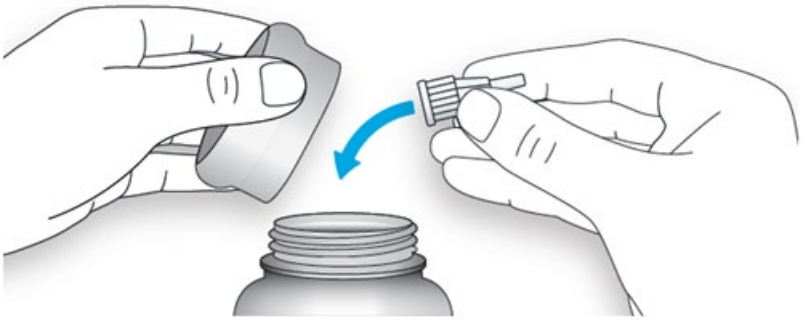



B. **Grip and squeeze the widest part of the outer needle cap.** Turn your pen several times with your other hand to remove the needle.

    - Try again if the needle does not come of the first time.

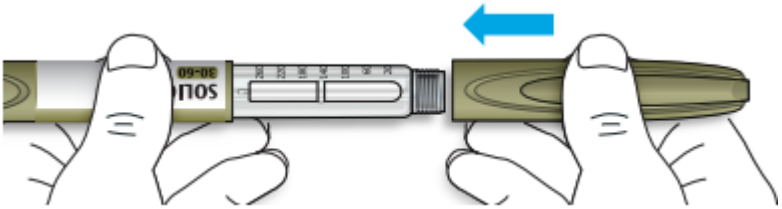



C. **Throw away the used needle in a puncture resistant container** (see **Throwing your pen away**).



**D. Put your pen cap back on.**

**b.** Do not put the pen back in the refrigerator.



**How to store your pen**

**Before first use:**

- Keep new pens in the refrigerator between 2 °C – 8 °C.
- **Do not** freeze.

**After first use:**

- Keep your pen at room temperature, at or below 25 °C.
- **Do not** put your pen back in the refrigerator.
- **Do not** store your pen with the needle attached.
- Store the pen with your pen cap on.
- Only use your pen for up to 28 days after its first use.

**How to care for your pen**

**Handle your pen with care**

- If you think that your pen may be damaged, do not try to fix it. Use a new one.

**Protect your pen from dust and dirt**

- You can clean the outside of your pen by wiping it with a damp cloth (water only). **Do not** soak, wash or lubricate the pen. This may damage it.

**Throwing your pen away**

- Remove the needle before throwing your pen away.
- Throw away your used pen as instructed by your pharmacist.