

PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE PHARMACISTS’
REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor’s prescription only

SULIQUA 100/33 SOLUTION FOR SUBCUTANEOUS INJECTION IN AN INJECTION PEN

Active ingredients

The active ingredients are:

Insulin glargine and lixisenatide.

For the list of inactive ingredients, see section 6 “Further information” and section 2 “Important information regarding some of the ingredients of Suliqua”.

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

Each mL contains 100 units of insulin glargine and 33 micrograms of lixisenatide.

Each ‘dose step’ of Suliqua contains one unit of insulin glargine and 0.33 micrograms of lixisenatide.

Read this leaflet carefully in its entirety before using the medicine.

Keep this leaflet; you may need to read it again.

This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

<p>In addition to the leaflet, Suliqua preparation also has a Patient Safety Information Card. This card contains important safety information that you need to know before starting treatment and during treatment with Suliqua and act accordingly.</p> <p>Read the Patient Safety Information Card and the patient leaflet before starting to use the preparation. Keep the card for later reading, if necessary.</p>
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1. WHAT IS THE MEDICINE INTENDED FOR?
Suliqua is intended, in combination with metformin, for treatment of adults with type 2 diabetes, to improve control of blood sugar levels when such control is not achieved by treatment with metformin alone or by treatment with metformin together with other medicines given orally to treat diabetes, or in combination with basal insulin.

Suliqua, a medicine for injection to treat diabetes, contains two active ingredients:
Insulin glargine - a long-acting insulin that helps control blood sugar (glucose) levels throughout the day.
Lixisenatide - a ‘GLP-1 analogue’ that helps the body produce its own additional insulin in response to increases in blood sugar levels, and slows the absorption of sugar from food.

2. BEFORE USING THE MEDICINE

<p>Do not use this medicine:</p> <p>If you are sensitive (allergic) to insulin glargine or to lixisenatide or to any of the other ingredients contained in this medicine (see section 6).</p>
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Special warnings regarding use of the medicine
Before treatment with the medicine, tell the doctor, nurse or pharmacist if:

- You have type 1 diabetes, as Suliqua is used to treat type 2 diabetes and therefore will not be suitable 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 suitable for you.
- You have a severe stomach or gut problem such as a disease of the muscles of the stomach called “gastroparesis” (paralysis of the stomach) which results in delayed stomach emptying. Since Suliqua may cause stomach side effects (see section 4), the medicine has not been studied in patients with severe stomach or gut problems. Read the information regarding medicines that should not stay too long in your stomach in the section “Drug interactions”.
- You have severe kidney disease or you are undergoing dialysis, as in this condition, use of this medicine will not be recommended.

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

Pay particular attention to the following:

- Too low blood sugar level (hypoglycemia). If your blood sugar level is too low, follow the instructions for hypoglycemia.
- Too high blood sugar level (hyperglycemia). If your blood sugar level is too high, follow the instructions for hyperglycemia.
- Ensure that you are using the right medicine. Always check the label before each injection to avoid confusing Suliqua and other insulins.
- If you suffer from poor eyesight, see section 3.

When using this medicine, pay attention to the following and consult with a doctor, pharmacist or nurse before using the medicine

- Severe pain in the stomach area that does not go away. This could be a sign of acute pancreatitis.
- Loss of fluids from the body (dehydration), e.g., in case of vomiting and diarrhea. It is very important to avoid dehydration by drinking plenty of fluids, especially during the first weeks of treatment with Suliqua.

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 the medicine”). 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 dosage or the dosage of your other antidiabetic medications.

Travel

Consult with your doctor before traveling. 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 the medicine.
- The possible effects of changing to different time zones.
- 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
There is no experience with Suliqua in children and adolescents aged less than 18 years; therefore, Suliqua is not recommended for use in this age group.

Drug interactions
If you are taking, have recently taken, or might take, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
If you use another anti-diabetes medicine, check with your doctor whether you should stop using it when starting treatment with Suliqua.

Some medicines may cause your blood sugar level to change. As a result, your doctor may need to change your Suliqua dosage. Therefore, before taking a medicine, ask your doctor if it can affect your blood sugar level and what action, if any, you need to take. You also need to be careful when you stop taking another medicine.

The effect of some medicines that you take might be affected by Suliqua. Some medicines such as antibiotics, oral contraceptives, statins (such as atorvastatin to lower cholesterol levels), tablets/capsules resistant to stomach degradation, granules or oral powder/suspension that should not stay too long in your stomach, may need to be taken at least one hour before or 4 hours after your Suliqua injection.

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

- Any other medicine to treat diabetes.
- Disopyramide – to treat some heart diseases.
- Fluoxetine – to treat depression.
- Sulfonamide antibiotics - to treat infections.
- Fibrates - for lowering high levels of blood fats.
- MAO (monoamine oxidase) inhibitors - for treating depression or Parkinson’s disease.
- ACE (angiotensin converting enzyme) inhibitors – to treat heart diseases or high blood pressure.
- Medicines to relieve pain and reduce fever, such as pentoxifylline, propoxyphene, salicylates (such as acetylsalicylic acid).
- Pentamidine – for treatment of some parasitic infections; may cause a too low blood sugar level, which may sometimes followed by a too high blood sugar level.

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

- Corticosteroids such as cortisone and prednisolone – to treat inflammation.
- Danazol – to treat endometriosis.
- Diazoxide – to treat high blood pressure.
- Protease inhibitors – to treat acquired immunodeficiency syndrome (AIDS, HIV).
- Diuretics – to treat high blood pressure or fluid retention.
- Glucagon – to treat very low sugar level.
- Isoniazid – to treat tuberculosis.
- Somatotropin - a growth hormone.
- Thyroid hormones – to treat thyroid gland problems.
- Estrogens and progestogens, such as oral contraceptives or use of estrogens to treat bone loss (osteoporosis).
- Clozapine, olanzapine and phenothiazine derivatives – to treat mental health problems.
- Sympathomimetic medicines such as epinephrine (adrenaline), salbutamol and terbutaline - to treat asthma.

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

- Beta blockers or clonidine – to treat high blood pressure.
- Lithium salts – to treat mental health problems.

Medicine that may reduce warning signs of a low blood sugar:

Beta-blockers and some other medicines (such as clonidine, guanethidine, reserpine – to treat high blood pressure) may make it harder to recognize warning signs of low sugar levels in your blood (hypoglycemia). They may even hide or stop the first warning signs that your blood sugar level is too low.

If you are taking any of the medicines listed above, or you are not sure, ask your doctor, nurse or pharmacist.

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 (INR test) to check your blood clotting.

Use of Suliqua and alcohol consumption

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

Pregnancy and breastfeeding

Do not use Suliqua during pregnancy. It is not known if Suliqua may harm your unborn child.

Do not use Suliqua if you are breastfeeding. It is not known if Suliqua passes into your milk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult with the doctor or pharmacist before taking this medicine.

Driving and using machines

Blood sugar levels that are too low or too high can affect your ability to drive or operate machines. Your ability to concentrate may be affected. This could be dangerous to yourself and others.

Consult the doctor about driving if:

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

Important information regarding some of the ingredients of Suliqua

Suliqua contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially “sodium-free”.

Suliqua contains metacresol

This medicine contains metacresol which may cause allergic reactions.

3. HOW TO USE THE MEDICINE?

Always use this preparation according to the doctor’s instructions. The dosage and treatment regimen will be determined by the doctor only. Your doctor may instruct you to take a different dosage of Suliqua compared to the dosage of the insulin you previously used. Check with the doctor, nurse or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Do not exceed the recommended dose.

Based on your lifestyle, your blood sugar test results and your previous insulin use, the doctor will instruct you:

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

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

How much to use?

Suliqua 100/33 Solution for Subcutaneous Injection in an **injection pen:**

- This pen provides a dose of 30 to 60 dose steps in one injection, in intervals of 1 dose step.
 - Each dose step that you select contains one unit of insulin glargine and 0.33 micrograms of lixisenatide.
- The Suliqua dose 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 Suliqua 100/50 solution for subcutaneous injection in an injection pen.

Do not inject a dose greater than 60 dose steps.

Many factors may affect your blood sugar level. You should be familiar with these factors so that you can take the right action if your blood sugar level changes and prevent it from becoming too high or too low.

Use in the elderly (65 years and over)

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

If you suffer from kidney or liver problems

If you suffer from kidney or liver problems, talk to your doctor, as you may need a lower dosage.

When to inject Suliqua?

Inject Suliqua once a day, within 1 hour before a meal.

It is preferable to inject Suliqua before the same meal every day, after you have chosen the meal most convenient for you.

Before injecting Suliqua

• Carefully follow the “Instructions for use” included in this leaflet and use the pen as described.

• If you do not follow the instructions, you may receive too much or too little Suliqua.

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.

Consult with your doctor or pharmacist if you are not sure.

How to inject?

- Suliqua is injected under the skin (subcutaneous - SC).
- Inject the medicine into the front of the thighs, upper arms or the front of the waist (abdomen).
- Change the injection place within the area you inject each day. This will reduce the risk of developing dents or lumps at the injection site (for more information, see “Additional side effects” in section 4).

Do not use Suliqua

- In a vein. This will change the way it works and may cause your blood sugar level to become too low.
- If you see particles in Suliqua. The solution must be clear, colorless and water-like.

Other important information about using the injection pens

- Always use a new needle for each injection. Reuse of needles increases the risk of blocked needles and may cause you to receive too high or too low a dosage. Dispose of the needles safely after each use.
- To prevent the possibility of transmitting infections from one person to another, do not use the same injection pen for more than one patient, even if the needle is changed.
- Only use needles that are compatible for use with the Suliqua pen (see “Instructions for Use”).
- A safety test must be performed before each injection (see “Instructions for Use”).
- Throw away the used needles in a special collection container.

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

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

- Throw away the pen and use a new one.
- Consult a doctor, pharmacist or nurse if you think there is a problem with your pen.

If you accidentally take a higher dosage

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

The first signs can appear in general in your body. Examples of signs indicating that your blood sugar level is going down too much or too fast, include: sweating, clammy skin, anxiety, fast or irregular heartbeat, high blood pressure and palpitations. These signs often occur before the signs of low sugar levels in the brain.

Additional signs include: headaches, intense hunger, nausea or vomiting, tiredness, sleepiness, restlessness, sleep disturbances, aggressive behavior, concentration difficulties, slow reactions, depression, confusion, speech disturbances (sometimes complete loss of ability to speak), vision changes, tremor, inability to move (paralysis), tingling in the hands or arms, feeling numb and tingling often around the mouth, dizziness, loss of self-control, being unable to look after yourself, fits and loss of consciousness.

If you forget to use Suliqua

If you skipped a dose of Suliqua or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycemia).

Signs indicative of hyperglycemia include:

Thirst, increased need to urinate, tiredness, dry skin, facial redness, loss of appetite, low blood pressure, fast heartbeat, glucose and ketone bodies in the urine. Stomachache, fast and deep breathing, sleepiness or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

When needed, Suliqua may 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 level and then inject your next dose at the usual time.

If you stop using Suliqua

Do not stop using Suliqua without consulting with the doctor. Discontinuation of use could lead to a very high blood sugar level (hyperglycemia) and a build-up of acid in the blood (ketoacidosis).

Adhere to the treatment regimen recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult a doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Suliqua may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you notice signs that your blood sugar level is too low (hypoglycemia), take action to increase your blood sugar level **straight away by eating glucose, a sugar cube or a sugar-sweetened drink.**

Hypoglycemia 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 level falls too low, you can become unconscious.

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

Additional side effects

Tell your doctor, nurse or pharmacist if you notice the following side effects:

- Skin changes at the injection site:**

If you inject insulin too often at the same place, the skin may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; it is not known how often these skin changes occur). The insulin may not work well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Common side effects may occur in up to 1 in 10 users

- Dizziness
- Nausea
- Vomiting
- Diarrhea

- Skin and allergic reactions at the injection site: The signs may include reddening, unusually intense pain when injecting, itching, rash, swelling or inflammation. The reaction may spread around the injection site. Most minor reactions to insulins disappear in a few days to a few weeks.

Uncommon side effects may occur in up to 1 in 100 users

- Cold, runny nose, sore throat
- Hives (urticaria)
- Headache
- Indigestion (dyspepsia)
- Stomachache

- Tiredness

If a side effect occurs, if a side effect worsens or if you are suffering from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/ or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use this medicine after the expiry date (exp. date) that appears on the label of the pen/carton.

The expiry date refers to the last day of that month.

Storage conditions:

Before first use:

Store in a refrigerator (2°C-8°C). Do not freeze or place near the freezer compartment or a freezer pack.

Keep the pen in the original carton to protect from light.

After first use or if the pen has been taken as a spare pen

The pen can be stored up to 14 days out of the refrigerator, at a temperature below 30°C.

Throw the pen away after this period.

Do not return the pen to the refrigerator and do not freeze. Store the pen far away from direct heat or from direct light.

When you are not using the pen, put the pen cap back on in order to protect from light.

Do not leave the pen in the car on a very hot or cold day.

Do not store the pen with a needle attached to it.

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

6. FURTHER INFORMATION

In addition to the active ingredients, Suliqua also contains: Glycerol (85%), Methionine, Metacresol, Zinc chloride, Concentrated hydrochloric acid, Sodium hydroxide, Water for injections. Also see section: “Important information regarding some of the ingredients of Suliqua”.

What Suliqua looks like and contents of the pack

Suliqua 100/33 is a clear, colorless solution for injection provided in a glass cartridge inserted into a Solostar injection pen.

Each Suliqua pen contains 3 mL of solution.

There are packs of 3 and 5 injection pens. Not all package sizes are marketed.

Needles are not included in the package.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.

Registration Holder and importer’s name and address: sanofi-aventis Israel Ltd., 10 Beni Gaon Street, Netanya.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 159-27-35118

Revised in January 2022 according to MOH guidelines.

INSTRUCTIONS FOR USE SULIQUA 100/33 SOLUTION FOR INJECTION WITH AN INJECTION PEN (30-60 DOSE STEPS)

Read the patient leaflet and these instructions for use before first use of Suliqua

The Suliqua 100/33 SoloStar pen contains insulin glargine and lisinsatide. The combination of these two medical preparations in this pen is intended for daily injection of 30 to 60 'dose steps' of Suliqua.

- **Never re-use the same needles.** If you do, you may not receive your full dose (rather, too small a dose) or you will receive too large a dose, since the needle may be blocked.
- **Never use a syringe to remove medicine from your pen.** If you do, you may not get the correct amount of the medicine. Keep these instructions for future use.

Important information

- Never share the pen – it is intended for you only.
- Never use the 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 extra needles in case they get lost or stop working.
- Always check the label of the pen before use to make sure that you have the right pen.

Learn to inject

- Before using the pen, consult a doctor, pharmacist or nurse about how to inject properly.
- If you have problems handling the pen, e.g., you have problems with your eyesight, ask for help.
- Read all of the instructions before using the pen. If you do not follow all of the instructions, you may get too much or too little medicine.

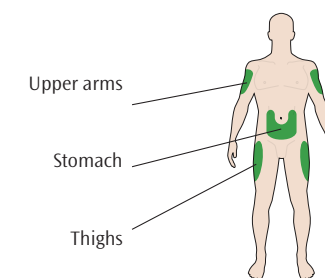
Need help?

- If you have any questions about Suliqua, the pen or about diabetes, ask the doctor, pharmacist or nurse.

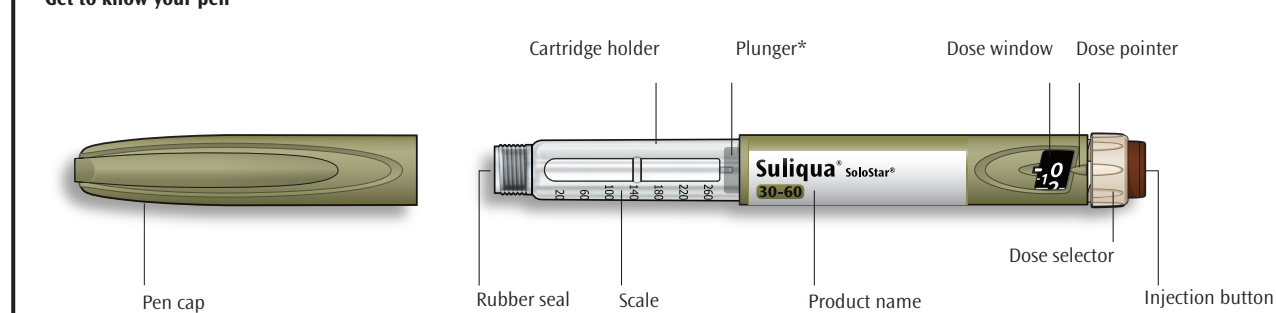
Extra items you will need

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

Injection sites



Get to know your pen



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

STEP 1 - CHECK YOUR PEN

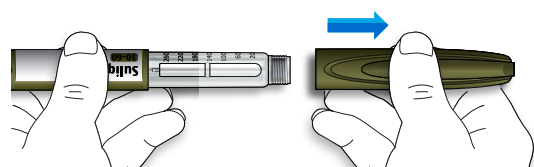
For first use of a new pen, take it out of the refrigerator at least **one** hour before the injection. Injecting cold medicine is more painful. After first use, the pen should be stored below 30°C.

A. Check the name and expiration date appearing on the label of the pen.

- Make sure you have the correct medicine. This pen is olive-colored, 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. Consult your doctor about which pen is suitable for your needs.**
- **Never** use the pen after its expiration date.

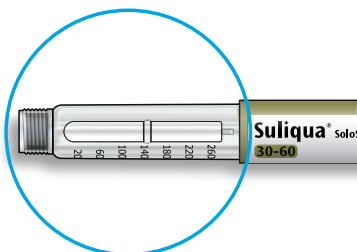


B. Remove the pen cap.



C. Check that the medicine is clear.

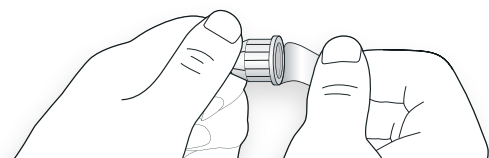
- Look at the transparent cartridge holder. **Do not** use the pen if the medicine looks cloudy, colored or contains particles.



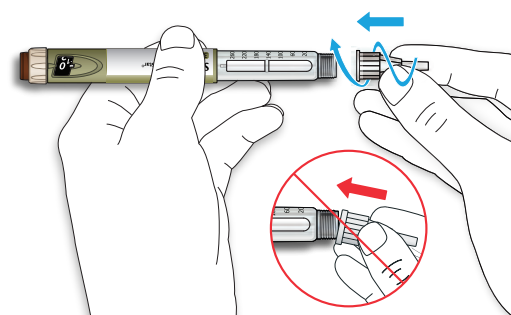
STEP 2 - ATTACH A NEW NEEDLE

- **Do not** re-use needles. Always use a new sterile needle for each injection. This helps prevent blockage of needles, contamination of the preparation or infection in the patient.
- Only use needles compatible with the Suliqua pen.

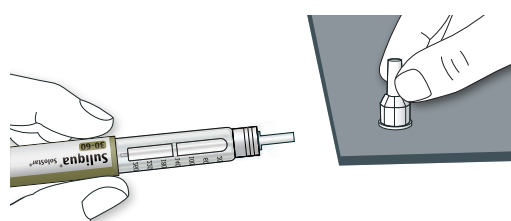
A. Take a new needle and peel off its protective seal.



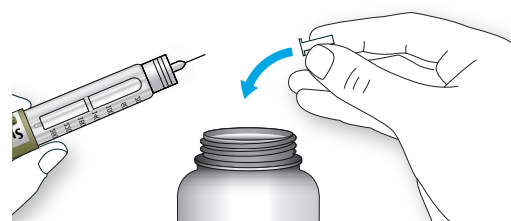
B. Keep the needle straight opposite the pen and screw it onto the pen until fixed in place. Do not over-tighten.



C. Pull off the outer needle cap. Keep it for later.



D. Pull off the inner needle cap and throw it away. If you try to put it back on, you may accidentally stick yourself with the needle.



Handling needles

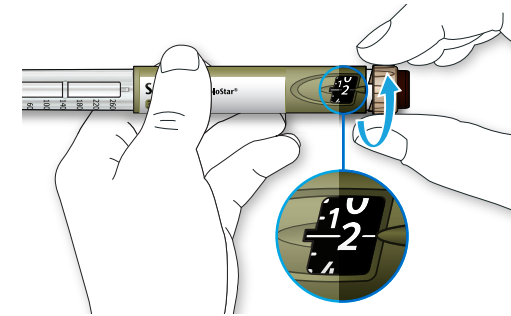
- Take care when handling needles – this is to prevent needle injury and cross-infection.

STEP 3 - DO A SAFETY TEST

Always do a safety test before each injection. This is to:

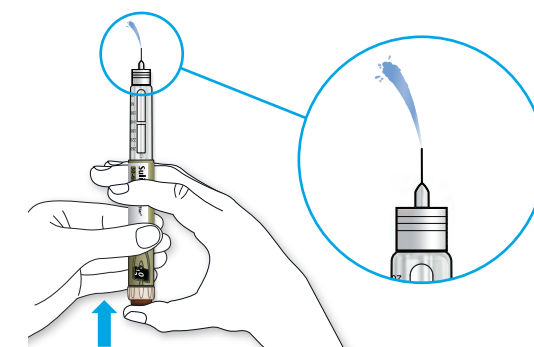
- Check that your pen and the needle are working properly.
- Make sure that you get the correct dose.

A. Select 2 dose steps by turning the dose selector until the dose pointer indicates the number 2.



B. Press the injection button all the way in.

- When the medicine comes out of the needle tip, your pen is working correctly; the dose selector will go back 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 the 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

- **Only use this pen 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 to the pen. This can damage the pen.

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



B. Turn the dose selector until the dose pointer points to your dose.

- If you turned past your dose, you can turn back again.
- 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 30 dose steps. Always use another Suliqua 30-60 SoloStar pen to complete your dose and no other pen.

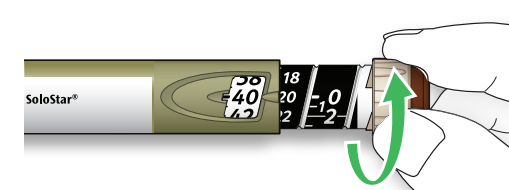
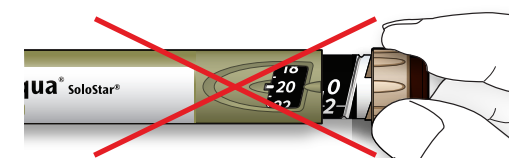
How to read the dose window

- Even numbers are presented in line with the dose pointer and odd numbers are presented as a line between even numbers.

39 units selected



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



Units of medicine in your pen

- Your pen contains 300 dose steps. You can select your dose in intervals of one dose step.
- **Do not** use this pen if you need a once-daily dose that is less than 30 dose steps or more than 60 dose steps. Discuss with your doctor which pen is suitable for your needs.
- Each pen contains more than one dose.

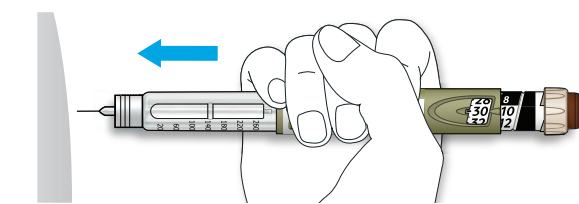
STEP 5 - INJECT YOUR DOSE

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

A. Choose an injection site as marked in the image of injection sites above.

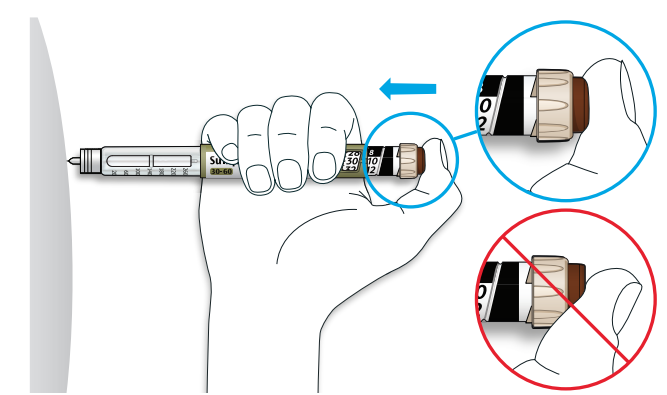
B. Push the needle into your skin as shown by your doctor, pharmacist or nurse.

- Do not touch the injection button yet.



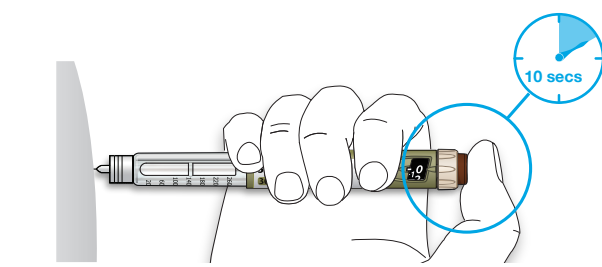
C. Place your thumb on the injection button. Then press all the way in and hold.

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



D. Keep the injection button pressed in and when you see "0" in the dose window, slowly count to 10.

- This is how you will get your full dose.



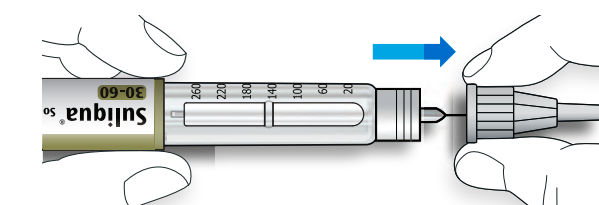
E. After holding and slowly counting to 10, release the injection button. Then remove the needle from the skin.

STEP 6 - REMOVE THE NEEDLE

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

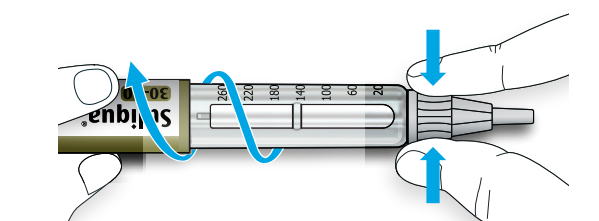
A. Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap. Then firmly press the cap back on.

- If put on at an angle, the needle may puncture the cap.

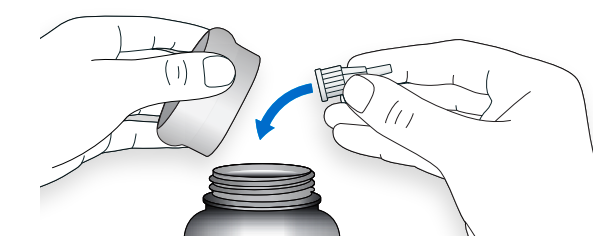


B. Grip and squeeze the widest part of the outer needle cap. Turn the pen a few times with your other hand, to remove the needle.

- If the needle doesn't come out the first time, try again.

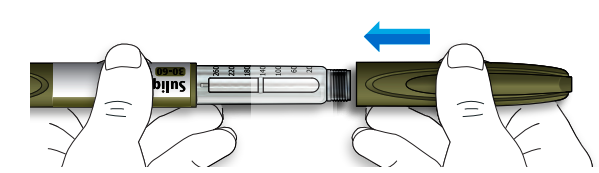


C. Throw away the used needle into a sharps container (see "Throwing your pen away", at the end of the Instructions for Use).



D. Put the pen cap back on.

- Do not put the pen back in the refrigerator.



How to store your pen

Before first use

- Store new pens (before first use) in the refrigerator, between 2°C and 8°C.
- **Do not** freeze.

After first use

- Store your pen at room temperature, **below 30°C**.
- **Do not** put your pen back in the refrigerator.
- **Do not** store your pen with the needle attached to it.
- Store your pen with the cap on it.
- Use the pen within up to **14 days** of first use.

How to care for your pen

Handle your pen carefully

- If you think that your pen is damaged, **do not** try to fix it; use a new pen.

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 a used pen in accordance with the instructions.