

PATIENT INFORMATION

When you are taking Suliqua

We have written this brochure for you who have diabetes and has been prescribed Suliqua (insulin glargine + lixisenatide) by your doctor. The primary goal in all diabetes treatment is to achieve a blood sugar level that is as normal as possible and at the same time to feel healthy.

If you have any questions regarding your diabetes treatment, don't hesitate to ask your nurse or doctor.

What Suliqua is and what it is used for

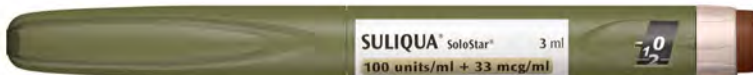
Suliqua is an injectable medication for diabetes that contains two active substances:

- insulin glargine – a type of long-acting insulin that helps to regulate the blood sugar 24 hours a day
- lixisenatide – a so-called GLP-1 analogue, which helps the body produce its own insulin as a response to blood sugar increases and also causes the sugar from food to be absorbed slower.

Suliqua is used as treatment of type 2 diabetes in adults, to regulate the blood sugar levels when they are too high. It is prescribed together with metformin when other medicines are not sufficient to control your blood sugar levels.

These other medications may include diabetes medicines in the form of tablets (such as metformin, sulfonylurea medicines) or insulin.

If you use another diabetes medicine, talk to your doctor about whether to stop taking that medication when you start using Suliqua.



How to use Suliqua

Always use this medication according to your doctor's instructions. Your doctor may tell you to use another dose compared to your previous insulin dose. Consult a doctor, pharmacy staff or a nurse if you have questions.

Depending on your lifestyle, the result from your blood sugar test, and your previous insulin treatment, your doctor will tell you:

- How much Suliqua you will need every day and at what time of day.
- When to check your blood sugar level and if you need to do a urine test.
- When you may have to increase or decrease your dose.

Your doctor may recommend that you use Suliqua together with other medications for high blood sugar.

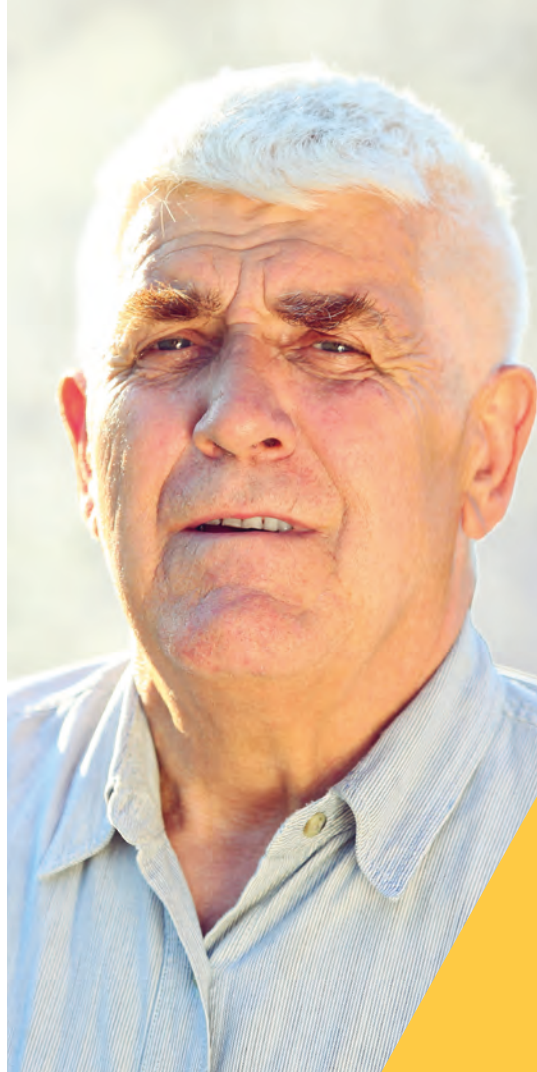


How much you should use

Suliqua 100 units/ml + 33 micrograms/ml pre-filled injection pen:

- This pen gives doses from 30 to 60 doses in one injection, provided in stepwise increments.
- Each incremental step you twist forward contains 1 unit of insulin glargine and 0.33 micrograms of lixisenatide.

Your Suliqua dose is given as incremental steps. The dose window on the injection pen shows the number of incremental units of Suliqua to be injected. Do not inject a dose larger than 60 units.



When to inject Suliqua

Use Suliqua once daily, within one hour before your meal. Suliqua should preferably be injected before the same meal each day, when you have selected the most suitable mealtime for you. Inject Suliqua in the stomach or the outside of the thigh. Do not forget to vary injection sites.

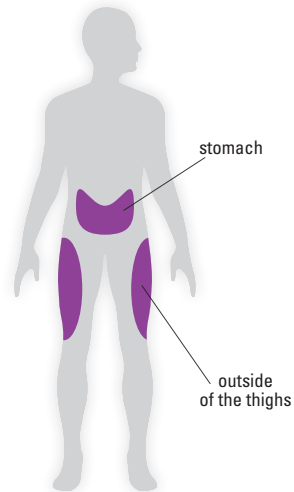
Before you inject Suliqua

- Always follow the instructions that accompany this patient information leaflet.
- If you do not follow all instructions you may get too much or too little Suliqua.

To avoid mistakes: Always check the medication carton and the label on the injection pen before each injection to ensure that you have the correct pen. This is especially important if you use more than one injection medication. Ask a doctor or pharmacy staff if you have questions.

If you have used too much Suliqua

If you have injected too much Suliqua, your blood sugar level may become low (hypoglycaemia). Check your blood sugar and eat more food to prevent your blood sugar from becoming too low.



When to inject Suliqua

If you have forgotten to use Suliqua

If you have forgotten a dose of Suliqua, or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycaemia). If needed, Suliqua can be injected before the next meal.

- Do not inject a double dose to make up for a forgotten dose.
- Do not take two injections per day.
- Check your blood sugar and then inject the next dose at your regular time.



How to store Suliqua

Store this medication out of sight and out of reach from children.

Use before the expiration date that is stated on the package and on the label on the pen after “EXP”. The expiration date is the last day of the stated month.

Before first use

Store in refrigerator (2°C-8°C).

Must not be frozen or stored in direct contact with freezer compartment or freezer block.

Store the injection pen in its outer box since it is sensitive to light.

After first use/spare pens

The injection pen can be stored for a maximum of 28 days outside of a refrigerator, but below 25°C. Discard the pen after this time period.

Must not be put back in refrigerator and must not be frozen. Store the injection pen away from direct heat or direct sunlight. The protective cap must be put back on the injection pen after each injection.

Do not leave the injection pen in a car on an extremely hot or cold day. Do not store the injection pen with the needle attached.

Medications must not be discarded in sewers or in household waste. Ask your pharmacy staff how to discard drugs that are no longer used. These measures are intended to protect the environment.

Other

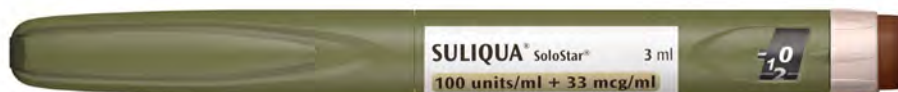
Reporting side effects

If you experience side effects, talk to a doctor, pharmacy staff or nurse. This also applies to any side effects that are not mentioned in this information.

By reporting side effects you may contribute to increasing the information about the safety of the medication.



Injection pen



Suliqua SoloSTAR® is a pre-filled injection pen where the dose is set in increments of 1 unit. The maximum dose is 60 units per injection.



Suliqua® (insulin glargine + lixisenatide) **R, F, A10AE54**, 100 units/ml + 50 micrograms/ml, fluid for injection, solution in a pre-filled injection pen and 100 units/ml + 33 micrograms/ml fluid for injection, solution in a pre-filled injection pen. **Indication:** Suliqua is intended for, in combination with metformin, treatment of adults with type 2 diabetes to improve the glycaemic control when sufficient control has not been achieved with only metformin or in combination with another oral glucose lowering medication or basal insulin. **Warnings and caution:** Suliqua should not be used in patients with type 1 diabetes mellitus or in treatment of diabetic ketoacidosis. For more information, see www.fass.se. **Packaging:** Suliqua SoloStar 3x3 ml pens and 5x3 ml pens. Sanofi AB, Box 30052, 104 25 Stockholm, tel: +46 8 634 50 00, www.sanofi.se. If you have questions about our medicines, please contact: infoavd@sanofi.com. Date for the latest review of the Summary of Product Characteristics: February, 2017.

▼ **This medication is subject to extended monitoring. For further information, see www.fass.se**



Notes

Questions about our diabetes products:
020-52 68 87

You can find more information about diabetes on www.insulin.se
You can also read about different insulins on www.fass.se

Read the patient information leaflet carefully!