



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Educational materials for healthcare professionals and patients using the diabetes medicine Suliqua

Measures intended to reduce risk of confusion between two pens of different strengths

Healthcare professionals and patients expected to use the diabetes medicine Suliqua will be given educational materials to ensure that the medicine is used correctly and prevent medication errors such as confusion between the two different strengths of the product.

Suliqua contains a combination of insulin glargine and a non-insulin medicine, lixisenatide. It is available as a solution for injection in pre-filled pens. As for similar combination medicines used for the treatment of diabetes, the dose of Suliqua is expressed in 'dose steps', with each dose step corresponding to one unit of insulin plus a fixed amount of lixisenatide.

Suliqua is available in two different pens:

- Suliqua containing 100 units/ml insulin glargine and 50 micrograms/ml lixisenatide. This pen can deliver between 10 and 40 dose steps per day (and is also referred to as Suliqua 10-40).
- Suliqua containing 100 units/ml insulin glargine and 33 micrograms/ml lixisenatide; This pen can deliver between 30 and 60 dose steps per day (and is also referred to as Suliqua 30-60)

Since the two pens contain different amounts of lixisenatide for each dose step, it is important that they are not used interchangeably as this would result in patients receiving too much or too little lixisenatide. This could lead to fluctuations in blood glucose control.

To reduce the risk of medication errors, educational materials will be sent out to relevant healthcare professionals in the EU where the product is marketed, to raise awareness about the differences between the two pens, the way the dose is expressed and how to use the medicine correctly.

Healthcare professionals should ensure that they train their patients on how to use Suliqua correctly. Patients will receive a 'patient guide' from their healthcare professional which they should read carefully along with the package leaflet.



Information for patients and carers

- Suliqua contains insulin glargine and a non-insulin medicine, lixisenatide.
- As for similar medicines containing insulin with a non-insulin medicine, the dose is expressed in dose steps. One dose step always contains one unit of insulin plus a fixed amount of lixisenatide. Before you use Suliqua be clear on how many dose steps you require. Your healthcare professional will give you this information.
- Suliqua is supplied in two pre-filled pens:
 - Suliqua 10-40 (containing insulin glargine 100 units/ml with lixisenatide 50 micrograms/ml) – this pen can deliver between 10 and 40 dose steps per day. It is used for people who need 10-40 units of insulin daily, with the appropriate dose of lixisenatide.



- Suliqua 30-60 (containing insulin glargine 100 units/ml with lixisenatide 33 micrograms/ml) – this pen can deliver between 30 and 60 dose steps per day. It is used for people who need 30-60 units of insulin daily, with the appropriate dose of lixisenatide.



- Because the two pens contain different concentrations of lixisenatide, the dose step of one pen is not equivalent to the dose step of the other.
- You must therefore not use the pens interchangeably as you could receive too much or too little lixisenatide and this could disrupt the control of your blood sugar levels.
- The dose counter of the pen device shows the number of dose steps to be injected. Your healthcare professional will train you on how to use the pen.
- When starting Suliqua and in the weeks thereafter you should measure your blood sugar levels more frequently than usual.
- Suliqua must only be used with its pre-filled pen. You must never use a syringe to remove the medicine from its pen as this may lead to dosing errors and serious harm.
- Read the instructions in your package leaflet carefully before using your medicine.
- If you have any questions about your treatment, speak to your healthcare professional.

Information for healthcare professionals

- Provide patients with the patient guide prior to prescribing or dispensing Suliqua.
- Ensure that patients and their caretakers are adequately informed on how to use their medicine.
- Suliqua is supplied in a pre-filled pen and must only be used with this device. A syringe must never be used to withdraw insulin glargine and lixisenatide from the pre-filled pen as this may lead to dosing errors and serious harm.

- Suliqua is a fixed combination of insulin glargine/lixisenatide available in two strengths:
 - Suliqua 10-40 (containing insulin glargine 100 units/ml with lixisenatide 50 micrograms/ml) - this pen can deliver between 10 and 40 dose steps per day. Suliqua 10-40 (containing insulin glargine 100 units/ml with lixisenatide 50 micrograms/ml) - this pen can deliver between 10 and 40 dose steps per day. It is used for people needing 10-40 units of insulin daily. The lixisenatide strength is higher to ensure an adequate dose in people requiring lower doses of insulin.



- Suliqua 30-60 (containing insulin glargine 100 units/ml with lixisenatide 33 micrograms/ml) - this pen can deliver between 30 and 60 dose steps per day. The lixisenatide strength is lower to ensure an adequate but not excessive dose in people requiring higher doses of insulin.



- Suliqua is given in dose steps which correspond to a set number of units of insulin plus a fixed amount of lixisenatide. One dose step always contains one unit of insulin, regardless of the Suliqua pen being used. The amount of lixisenatide per dose step however varies (0.50 micrograms per dose step for the 10-40 pen and 0.33 micrograms per dose step for the 30-60 pen).

The doses of insulin and lixisenatide contained in increasing dose steps are given in the figure below:

Suliqua (insulin glargine 100 units/ml with lixisenatide 50 micrograms/ml) 10-40 pen				
	10 dose steps	20 dose steps	30 dose steps	40 dose steps
dose of insulin glargine (units)	10	20	30	40
dose of lixisenatide (micrograms)	5	10	15	20

Suliqua
(insulin glargine 100 units/ml with lixisenatide 33 micrograms/ml)
30-60 pen

	30 dose steps	40 dose steps	50 dose steps	60 dose steps
dose of insulin glargine (units)	30	40	50	60
dose of lixisenatide (micrograms)	10	13	16.5	20

- Explain to your patient that the dose counter of the pen device shows the number of dose steps to be injected. The prescription must state the type of pen to be used (either Suliqua 10-40 or Suliqua 30-60), the strength (i.e. insulin glargine 100 units/ml + lixisenatide 50 micrograms/ml or insulin glargine 100 units/ml + lixisenatide 33 micrograms/ml) and the number of dose steps to be administered.
- Explain the design and features of the pen to the patient and if the patient has been transferred from another pen device, highlight the differences in design between the two devices to avoid confusion (focus on colour differentiation, warning statements on carton/label).
- Patients who are blind or with poor vision must be instructed to always get assistance from another person who has good vision and is trained in using the Suliqua pen device.
- Tell patients to closely monitor their blood sugar levels when starting Suliqua and in the weeks thereafter.
- Pharmacists are encouraged to check that patients and carers are able to read the strength of Suliqua, the dose range of the pre-filled pen and the dose counter of the pen device before dispensing Suliqua. Pharmacists should also check that patients have been trained on how to use the pen.
- Pharmacists should clarify with the prescriber any incomplete prescription.

More about the medicine

Suliqua is a medicine that is used for the treatment of type-2 diabetes. It is used together with diabetes medicines taken by mouth in adults whose blood glucose (sugar) levels are not satisfactorily controlled by metformin alone or metformin combined with either a glucose-lowering medicine or insulin.

The active substances in Suliqua are insulin glargine and lixisenatide.

More information about Suliqua can be found on the Agency's website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004243/human_med_002064.jsp