SOLIQUA™
insulin glargine & lixisenatide injection

Version No.: 2.0 - Sep 2021

SOLIQUA™ is supplied in a pre-filled pen and must only be used with this device; healthcare professionals must never use a syringe to withdraw SOLIQUA™ from a pre-filled pen or dosing errors and serious harm can result.

Refer to the SOLIQUA Summary of Product Characteristics for additional prescribing recommendations.

For reporting adverse events: Please report medication errors or any side effects suspected to be associated with the use of the SOLIQUA SoloStar pen to Sanofi, either by telephone +966 544284797 or by email KSA_pharmacovigilance@sanofi.com.

The aRMM "Additional Risk Minimization Measures" are approved by SFDA
This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

To the National Pharmacovigilance Centre (NPC):
SFDA call center: 19999,
E-mail: npc.drug@sfda.gov.sa,
Website: https://ade.sfda.gov.sa/

For additional information and / or questions, or if you require additional copies of this educational material,
please call Sanofi medical infromation at +966-12-669-3318, or send e-mail to ksa.medicalinformation@sanofi.com

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SANOFI

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GUIDE FOR HEALTHCARE PROFESSIONALS

INTRODUCING SOLIQUA™ (INSULIN GLARGINE 100 UNITS/mL + LIXISENATIDE) AVAILABLE IN 2 PREFILLED PENS CONTAINING DIFFERENT DOSAGE STRENGTHS.

IMPORTANT SAFETY INFORMATION

Avoiding medication errors with SOLIQUA (insulin glargine 100 units/ml + lixisenatide) – available in 2 pre-filled pens containing different dosage strengths.

- This document is supplied only as a guide to avoid medication errors. Please refer to the Summary of Product Characteristics before prescribing and dispensing.
- Please provide your patients with the Patient guide prior to prescribing or dispensing for the first time or when switching to a new pen to ensure that your patients and their caregivers are adequately informed on how to use SOLIQUAto help reduce the risk of medication errors.

A CHECKLIST FOR HEALTHCARE PROFESSIONALS

EXPLAIN TO YOUR PATIENT

- ☐ You are prescribing a number of dose steps that corresponds to a set number of Units of insulin glargine 100 U/mL plus a corresponding amount of lixisenatide.
- ☐ For SOLIQUA™, one dose step always contains one Unit of insulin glargine 100 U/mL, regardless of the SOLIQUA™ pre-filled pen being used (the SOLIQUA™ [10-40] pen or the SOLIQUA™ [30-60] pen).
- ☐ The dose pointer shows the number of dose steps to be injected.
- ☐ If your patient has been transferred from a different pre-filled pen device, highlight the differences in design between the two devices (focus on color differentiation and warning statements on packaging/label).
- ☐ Explain what the patient should anticipate regarding dysglycaemia and potential adverse reactions. For a complete list of adverse events, please refer to the SOLIQUA™ Summary of Product Characteristics.
- ☐ Patients who are blind or have poor vision must be instructed to always get assistance from another person who has good vision and is trained in the SOLIQUA™ SoloStar® pen device.
- ☐ Instruct your patients to always use a new needle before each use and to never use a syringe to remove the solution from the pen to avoid dosing errors and potential overdose.
- ☐ Recommend that your patients read the patient guide and the patient information leaflet carefully, as well as the instructions for use leaflet provided in the SOLIQUA™ SoloStar® packaging.
- ☐ Tell patients to closely monitor their blood sugar levels when starting SOLIQUA™, which contains insulin glargine 100 IU /mL and a non-insulin active substance (lixisenatide).

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SOLIQUA™ is available in two different pens:

- SOLIQUA™ containing 100 units/ml insulin glargine and 50 micrograms/ml lixisenatide. This pen should be used to deliver between 10 and 40 dose steps per day (and is also referred to as SOLIQUA™ 10-40). This pen is peach colored with an orange injection button.
- SOLIQUA™ containing 100 units/ml insulin glargine and 33 micrograms/ml lixisenatide. This pen should be used to deliver between 30 and 60 dose steps per day (and is also referred to as SOLIQUA™ 30-60). This pen is olive colored with a brown injection button.

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 including this "HCP guide" and a "Patient guide" are sent out to relevant healthcare professionals in countries where the product is marketed and the two pens are launched, to raise awareness about the differences between the two pens, the way the dose is expressed and how to use SOLIQUA™ correctly.

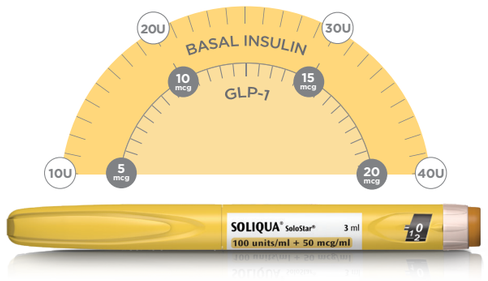
As Healthcare professionals, you should:

- Train your patients on how to use SOLIQUA™ correctly.
- Give to your patients the "Patient guide" which they should read carefully along with the package leaflet.

IMPORTANT INFORMATION ON DOSING

SOLIQUA™ 10-40 PEN

SOLIQUA™ 100 UNITS/mL + 50 MICROGRAMS/mL
SOLUTION FOR INJECTION IN A PRE-FILLED PEN

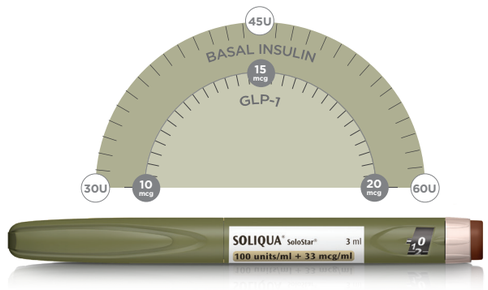


FIXED RATIO 2:1

- Insulin glargine (100 Units/mL): 10 – 40 Units/day
- Lixisenatide (50 mcg/mL): 5 – 20 mcg/day
- This pen allows a single once-daily injection of a dose between 10 and 40 dose steps
- This pen is peach coloured with an orange injection button

SOLIQUA™ 30-60 PEN

SOLIQUA™ 100 UNITS/mL + 33 MICROGRAMS/mL
SOLUTION FOR INJECTION IN A PRE-FILLED PEN



FIXED RATIO 3:1

- Insulin glargine (100 Units/mL): 30 – 60 Units/day
- Lixisenatide (33 mcg/mL): 10 – 20 mcg/da
- This pen allows a single once-daily injection of a dose between 30 and 60 dose steps
- This pen is olive coloured with a brown injection button

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STARTING DOSE TABLE

- Therapy with basal insulin or glucagon-like peptide-1 (GLP-1) receptor agonist or oral glucose lowering medicinal product other than metformin and SGLT-2 inhibitors should be discontinued prior to initiation of SOLIQUA™.
- The dose must be individualized based on clinical response and is titrated based on the patient's need for insulin.
- The starting dose of SOLIQUA™ is based on previous anti-diabetic treatment, and in order not to exceed the recommended lixisenatide starting dose of 10 mcg.

		PREVIOUS THERAPY		
		Insulin-naive patients (Oral antidiabetic treatment (insulin-naive patients)	Insulin glargine (100 Units/mL)* ≥20 to <30 Units	Insulin glargine (100 Units/mL)* ≥30 to ≤60 Units
Starting dose and pen	SOLIQUA™ (10-40) Pen	10 dose steps (10 Units/5 mcg)**	20 dose steps (20 Units/10 mcg)**	
	SOLIQUA™ (30-60) Pen			30 dose steps (30 Units/10 mcg)**

* If a different basal insulin was used:
- For twice daily insulin or insulin glargine (300 Units/mL), the total daily dose previously used should be reduced by 20% to choose the SULIQUA™ starting dose.
- For any other basal insulin, the same rule as for insulin glargine (100 Units/mL) should be applied.

** Units insulin glargine (100 Units/mL)/mcg lixisenatide.

- The maximum daily dose is 60 units insulin glargine and 20 mcg lixisenatide corresponding to 60 dose steps. For total daily doses >60 dose steps/day, SOLIQUA™ must not be used.
- The prescription must state the dose range and strength of the SOLIQUA™ pre-filled pen and the number of dose steps to be administered.

PHARMACIST GUIDANCE

Before dispensing SOLIQUA™, you should:

- Clarify with the prescriber any incomplete prescription.
- Check with the patient that the dispensed pen corresponds to the strength of pen the patient is expecting.
- Check that patients or caretakers are able to read the dose range and the dose pointer of the pre-filled pen.
- Check that patients have been trained on how to use the pen.