SOLIQUA™
insulin glargine & lixisenatide injection

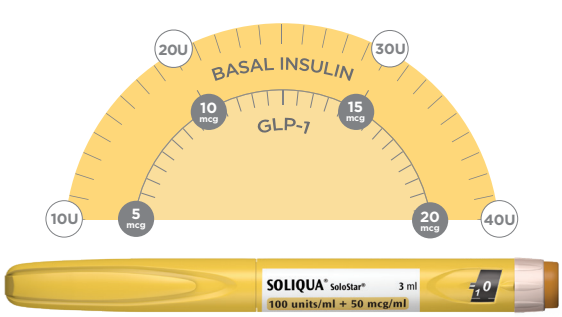
Version No.: 1.0 - July 2019

GUIDE FOR HEALTHCARE PROFESSIONALS

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

SOLIQUA™ 10-40 PEN

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

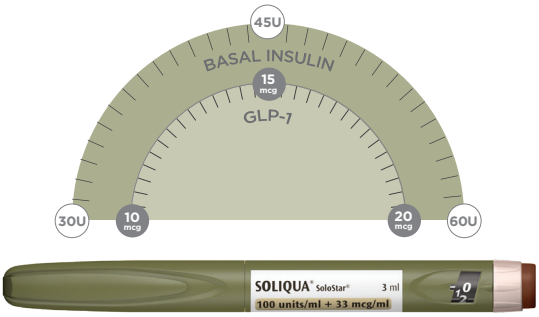


FIXED RATIO 2:1

- Insulin glargine (100 Units/mL): 10 – 40 Units/day
- Lixisenatide (50 mcg/mL): 5 – 20 mcg/day

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/day

- This document is supplied only as a guide. Please refer to the summary of product characteristics before prescribing and dispensing either of the SOLIQUA™ SoloStar® pens.
- Please provide your patients with the patient guide prior to prescribing or dispensing SOLIQUA™ to ensure that your patients and their caretakers are adequately informed on how to use SOLIQUA™.

The RMPs "Risk Minimization Plan" are approved by SFDA
This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

SANOFI

Version No: 1.0 - July 2019

IMPORTANT INFORMATION ON DOSING

SOLIQUA™ is available in 2 pre-filled pens containing different strengths of lixisenatide and different dose ranges of insulin glargine 100 U/mL, to treat patients with different insulin needs up to 60 Units:

- Both SOLIQUA™ SoloStar® pens simultaneously deliver insulin glargine 100 U/mL and the prandial glucagon-like peptide-1 receptor agonist (GLP-1 RA) lixisenatide in 2 different fixed-ratio solutions for a single, once-daily injection.
- Both pre-filled pens contain insulin glargine in a strength of 100 Units/mL.
- The SOLIQUA™ (10-40) pen allows a daily injection of doses between 10 and 40 dose steps (strength: insulin glargine 100 Units/mL and lixisenatide 50 mcg/mL; dose range: 10 to 40 Units of insulin glargine in combination with 5 to 20 mcg lixisenatide). This pen is peach colored with an orange injection button.
- The SOLIQUA™ (30-60) pen allows a once- daily injection of doses between 30 and 60 dose steps (strength: insulin glargine 100 Units/mL and lixisenatide 33 mcg/mL; dose range: 30 to 60 Units insulin glargine in combination with 10 to 20 mcg lixisenatide). This pen is olive colored with a brown injection button.

STARTING DOSE TABLE

- The dose must be individualised based on clinical response and is titrated based on the patient's need for insulin.

		PREVIOUS THERAPY		
		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 prescription must state the dose range and strength of the SOLIQUA™ pre-filled pen and the number of dose steps to be administered.
- The maximum daily dose is 60 dose steps (60 Units insulin glargine and 20 mcg lixisenatide).

Version No: 1.0 - July 2019

DOSAGE TITRATION

SOLIQUA™ is to be dosed in accordance with the individual patient's need for insulin. It is recommended to optimise glycaemic control via dose adjustment based on a fasting plasma glucose. Close glucose monitoring is recommended during the transfer and in the following weeks.

- For doses >40 dose steps/day titration must be continued with SOLIQUA™ (30-60) pen.
- For total daily doses >60 dose steps/day, SOLIQUA™ must not be used.

STORING THE SOLIQUA™ PENS

- Unopened SOLIQUA™ pens can be stored in the refrigerator until expiration date; once opened, discard after 14 days. The shelf-life is 24 months.

UNOPENED PEN

- Store, in the refrigerator with pen cap on at temperature between 2 °C and 8 °C, in the box it came in*
- Can be refrigerated until expiration date
- Do not freeze† Keep in the outer carton to protect from light
- Discard after expiration date has passed

OPENED PEN

- Keep at room temperature below 30 °C
- Do not refrigerate or freeze an opened SoloStar® pen
- Keep out of direct heat and light Put pen cap back on the pen after each injection
- Discard 14 days after opening

*Before injecting SULIQUA™, remove it from the refrigerator for at least one hour–cold insulin can be painful to inject.

†Do not allow SULIQUA™ to freeze. Do not put it in a freezer or next to a freezer pack. If you see frost or ice crystals in the SULIQUA™ solution, throw it away.

PHARMACIST GUIDANCE

- Pharmacists are encouraged to check that patients and caretakers are able to read the strength of SOLIQUA™, the dose range of the pre-filled pen, and the dose pointer of the pre-filled pen before dispensing SOLIQUA™.
- Pharmacists should also check that patients have been trained on how to use the pen.
- Pharmacists should clarify with the prescriber any incomplete prescription.

SANOFI

SOLIQUA™
insulin glargine & lixisenatide injection

Version No.: 1.0 - July 2019

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 U/mL and a non-insulin active substance (lixisenatide).

IMPORTANT SAFETY INFORMATION

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 Medical Information, please contact: **+966-12-6693318** or
ksa.medicalinformation@sanofi.com

In case of any drug related adverse events, please contact:
The National Pharmacovigilance Center (NPC)
Fax: **+966-11-205-7662**
Call Center: **19999**
E-mail: **npc.drug@sfda.gov.sa**
Website: **https://ade.sfda.gov.sa/**

For Pharmacovigilance, please contact:
+966-544-284-797, Ksa_pharmacovigilance@sanofi.com

For extra copies please contactSanofi: Mobile +966-540-447-861, Phone +966-12-669-3318, ext. 1697.

SANOFI