This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

SANOFI

24-July -2019

Direct Healthcare Professional Communication (DHPC)

Introducing Soliqua™ (Insulin Glargine 100 Units/Ml + Lixisenatide) — Available In 2 Pre-Filled Pens Containing Different Dosage Strengths

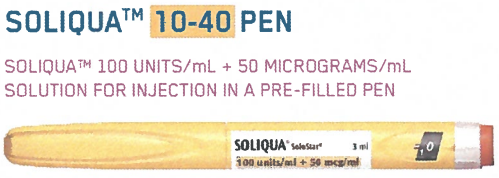
Dear Healthcare Professional,

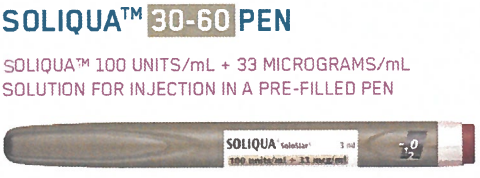
The purpose of this letter is to provide important information about dosing for your prescription of SOLIQUA™ which is indicated in combination with metformin for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin.

Summary

SOLIQUA™ is a fixed ratio combination of 2 products approved in Europe: insulin glargine 100 Units/mL (Lantus®) and lixisenatide (Lyxumia®). SOLIQUA™ is available in 2 pre-filled pens containing different strengths of lixisenatide and different dose ranges of insulin glargine 100 Units/mL to treat patients with different insulin needs up to 60 Units:

- 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 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.
- Both combinations of SOLIQUA™ are available with the SoloStar® pen technology.





Enclosed you will find a more detailed guide with additional information for your reference. Educational guides for patients are also included with this correspondence for distribution to patients treated with SOLIQUA™.

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Enclosed: SULIQUA™ guide for healthcare professionals, guide for patients, Summary of Product Characteristics, patient information leaflet, and instructions for use.

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In case of any drug related adverse events, please contact:
The National Pharmacovigilance Center (NPC)
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E-mail: npc.drug@sfda.gov.sa
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Kind Regards,

Anas Banaggar

Deputy Qualified Person Responsible for Pharmacovigilance

Signed on behalf of Qualified Person Responsible for Pharmacovigilance

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