For adults with T2D uncontrolled on basal insulin + OADs

SoliMix

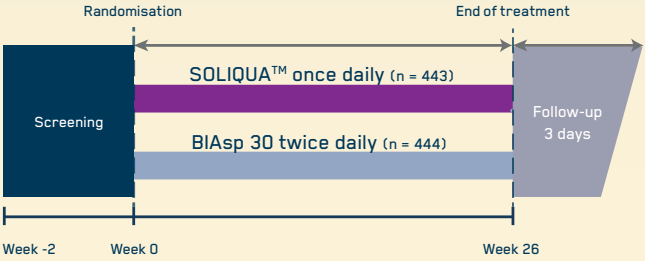
CHOOSE SOLIQUA™

FOR THE POWER TO GET TO TARGET

SoliMix supports the use of SOLIQUA™ as a favourable alternative to premix insulin when intensifying from BI + OADs:[1‡]

The first HEAD-TO-HEAD, randomised controlled trial* comparing SOLIQUA™ to premix insulin†

A multicentre, open-label, parallel group trial in adults with T2D uncontrolled on basal insulin + OADs[3]



Patients were monitored during screening, throughout the trial, and during follow-up using interactive response technology, on-site visits, and telephone visits for a total of 11 sessions.

SOLIQUA™ is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors.[2]

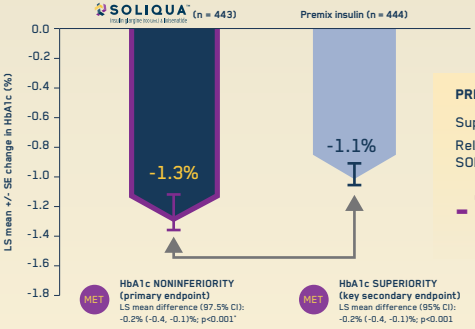
*SoliMix was a multicentre, open-label, parallel group, randomised, controlled trial to compare SOLIQUA™ vs BIAsp 30 in patients with T2D (n = 887) who failed to achieve glycaemic control with BI and OADs. Primary endpoints were non inferiority of SOLIQUA™ vs BIAsp 30 on HbA1c change from baseline to Week 26 and superiority of SOLIQUA™ vs BIAsp 30 on weight change from baseline to Week 26. Key secondary endpoints included proportion of patients reaching HbA1c target <7% without weight gain at Week 26; proportion of patients reaching target without hypoglycaemia (plasma glucose <70 mg/dl) and weight gain at Week 26; and superiority of SOLIQUA™ vs BIAsp 30 in HbA1c reduction.[1]

†BIAsp 30 (30% insulin aspart + 70% insulin aspart protamine).

‡Adults who have been treated with any BI combined with 1 or 2 OADs that could be metformin alone or metformin + an SGLT2 inhibitor.[2]

SOLIQUA™ achieved superior HbA1c reduction vs premix insulin[1]

REDUCTION IN HbA1c FROM BASELINE TO WEEK 26



PRIMARY ENDPOINT:

Superior HbA1c reduction

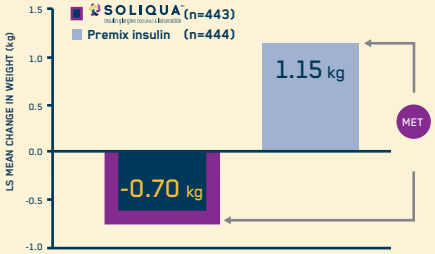
Relative reduction by SOLIQUA™ vs premix insulin

-18.2%

Analyses of the primary and key secondary efficacy endpoints were performed using the intention-to-treat population.

SOLIQUA™ achieved superior weight change vs premix insulin[1]

CHANGE IN WEIGHT FROM BASELINE TO WEEK 26



PRIMARY ENDPOINT:

Superior weight change

-1.86 kg

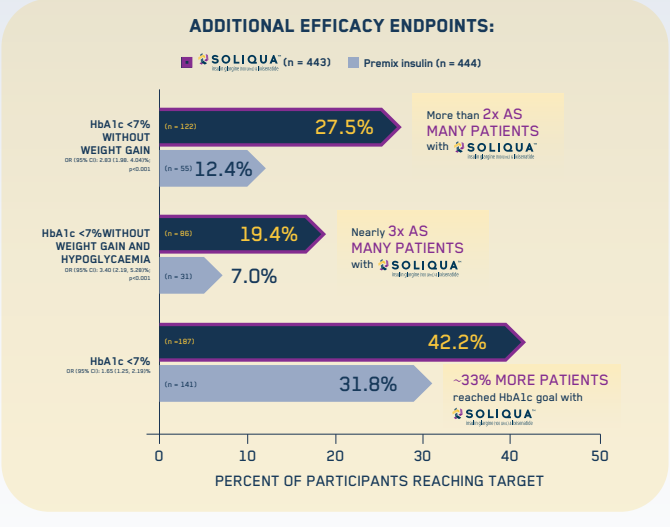
LS mean difference

(95% CI: -2.28, -1.43); p<0.001

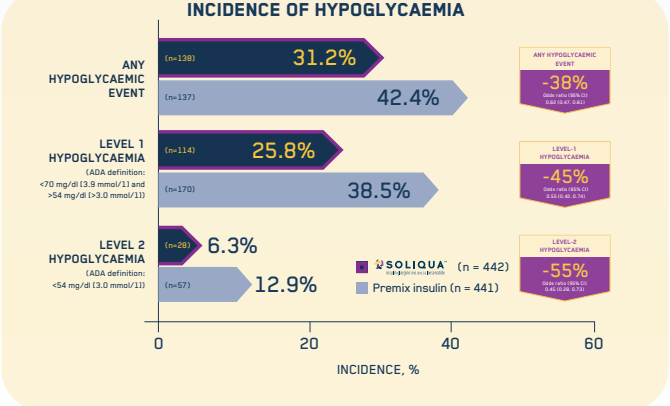
Mean baseline weight (+/- SD) was 80.7 kg +/- 16.5 kg for SOLIQUA™ vs 82.2 kg +/- 18.5 kg for premix insulin.

*Non-inferiority p-value was calculated using a non-inferiority margin of 0.3%.

With SOLIQUA™, more patients achieved HbA1c <7%, HbA1c <7% without weight gain and HbA1c <7% without weight gain and hypoglycaemia* vs premix insulin[1]



Lower incidence of hypoglycaemia* was observed with SOLIQUA™ vs premix insulin[1]



*Hypoglycaemia was defined as plasma glucose (PG) <70 mg/dl having occurred at any point within the 26-week treatment period. Post hoc analysis of nocturnal hypoglycaemia, defined as occurring between bedtime and waking, and between 00:00 h – 06:00 h, is not included here. Severe hypoglycaemia, an event requiring external assistance for recovery, was rare with only 1 episode for SOLIQUA™ and 2 in the premix insulin group. Overall safety and tolerability profiles of SOLIQUA™ and premix insulin were consistent with the known safety profile of each product. Gastrointestinal (GI) disorders were more common in the SOLIQUA™ group vs premix insulin: nausea 7.7% vs 0.0%, vomiting 1.1% vs 0.2%, and dyspepsia 0.9% vs 0.2%, respectively.[1,4†]

†The higher incidence of AEs observed for SOLIQUA™ vs premix insulin was due to nausea and led to treatment discontinuation in 0.5% of patients. Over the 26-week treatment period, 32.6 % of SOLIQUA™ patients and 27.7% of premix insulin patients reported treatment-emergent adverse events; 2.7% vs 2.9%, respectively, reported serious adverse events. The rate of discontinuation due to any adverse event was 0.9% for each group.

Upgrading your patient to SOLIQUA™ 100/50[2]

Insulin-naïve

Starting:

10

dose steps†

Insulin-experienced

(iGlar >20-<30)*

Starting:

20

dose steps†

Simple titration (per week)[2,5]

-4 | -2 | dose steps | +2 | +4

Target FPG
(4.4–5.6 mmol/L)

Once daily dosing:
Administer subcutaneously once daily within 1 hour prior to any meal

*If a different basal insulin was used: For twice daily basal insulin or insulin glargine (300 units/mL), the total daily dose previously used should be reduced by 20% to choose the SOLIQUA™ starting dose. For any other basal insulin, the same rule as for insulin glargine (100 units/mL) should be applied.
†Fixed ratio 2:1, 10 to 40 dose steps per injection, each dose step contains 1U of insulin glargine & 0.5 mcg of lixisenatide.

BI, basal insulin; CI, confidence interval; LS, least squares; OADs, oral antidiabetic drugs; SD, standard deviation; SE, standard error; SGLT2, sodium-glucose cotransporter-2; T2D, type 2 diabetes.

References: 1. Rosenstock J, et al. Diabetes Care. 2021:dc210393. 2. SOLIQUATM SmPC as of July 2020. 3. McCrimmon RJ, et al. Diabetes Obes Metab. 2021;23(6):1221-1231. 4. DoF 15017 study results. 5. Rosenstock J, et al. Diabetes Care. 2016;39:2026-2035.

Presentation: 100 units of insulin glargine and 33 micrograms lixisenatide in prefilled pen AND 100 units of insulin glargine and 50 micrograms lixisenatide in prefilled pen. Indications: For the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors. Dosage: The dose must be individualised based on clinical response and is titrated based on the patient's need for insulin. The lixisenatide dose is increased or decreased along with insulin glargine dose and also depends on which pen is used. Please refer to the full prescribing information for guidelines. Administration: Subcutaneous injection in the abdomen, deltoid, or thigh. Injection sites should be rotated within the same region from one injection to the next. Soliqua must not be drawn from the cartridge of the pre-filled pen into a syringe. Contraindications: Hypersensitivity to the active substances or to any of the excipients. Patients with type 1 diabetes mellitus. Treatment of diabetic ketoacidosis. Precautions: Elderly: Soliqua can be used in elderly patients. Progressive deterioration of renal function may lead to a steady decrease in insulin requirements. Renal impairment: Not recommended in severe renal impairment and end-stage renal disease. Frequent glucose monitoring and dose adjustment may be necessary in patients with mild to moderate renal impairment. Hepatic impairment: Frequent glucose monitoring and dose adjustment may be necessary. Hypoglycaemia may occur if dose is higher than required. Advise patients to take precautions to avoid hypoglycaemia while driving and using machines. Discontinue Soliqua if pancreatitis is suspected. Restart lixisenatide if acute pancreatitis is confirmed. Exercise caution in patients with pancreatitis history. Not recommended in patients with severe gastrointestinal disease. Use with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption. Potential risk of dehydration. Use may cause formation of antibodies against insulin glargine and/or lixisenatide. Always check pen label before each injection to avoid accidental mix-ups. Soliqua was not studied in combination with DPP-4 inhibitors, sulfonylurea, glinides, and pioglitazone. Interactions: Effects enhanced by anti-hyperglycaemics, ACEI, disopyramide, fibrates, fluoxetine, MAOIs, pentoxifylline, propoxyphene, salicylates, sulphonamide antibiotics. Effects reduced by corticosteroids, danazol, diazoxide, diuretics, glucagon, isoniazid, oestrogens and progestogens, phenothiazine derivatives, somatropin, sympathomimetics, thyroid hormones, atypical antipsychotics and protease inhibitors. Beta-blockers, clonidine, lithium or alcohol may either potentiate or weaken the effects of insulin. Pentamidine may cause hypoglycaemia, followed by hyperglycaemia. The signs of adrenergic counter-regulation may be reduced or absent under the influence of sympatholytic medicinal products such as beta-blockers, clonidine, guanethidine and reserpine. Fertility, pregnancy and lactation: Soliqua should not be used during pregnancy and breast-feeding. It is unknown whether insulin glargine or lixisenatide is excreted in human milk. Overdose: Overdose may lead to hypoglycaemia and gastrointestinal adverse reactions. Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates. More severe episodes with coma, seizure or neurologic impairment may be treated with glucagon (intramuscular or subcutaneous) or concentrated glucose solution (intravenous). Undesirable effects: Hypoglycaemia is very common. For common, uncommon and not known undesirable effects, please refer to the full prescribing information. Storage: Before first use: Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light. After first use: Store below 25°C. Use within 28 days. Do not refrigerate or freeze. Preparation: Soliqua 3 x 3ml prefilled pen, 5 x 3ml prefilled pen. Legal Classification: Part 1, First & Third Schedules Poison Full prescribing information is available upon request.

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SANOFI

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SOLIQUA™
insulin glargine (100 U/mL) & lixisenatide

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