Pursuing glycaemic control in type 1 diabetes

This promotional meeting is organised and funded by Sanofi. Prescribing Information and Adverse event reporting can be found at the end of this presentation.

MAT-GB-2001385 (V4.0) Date of preparation: December 2022

Toujeo indication: Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

Speaker Disclosure

Toujeo®
insulin glargine 300U/mL

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Pursuing glycaemic control in type 1 diabetes

The majority of adults fail to achieve HbA_{1c} ≤7%

SAGE study primary endpoint: Percentage of people at target HbA_{1c} of 7%

Global: 24.3%
(95% CI, 22.9—25.6)

26—44 years
27.6%
(95% CI: 25.5, 29.8)

45—64 years
21.0%
(95% CI: 19.0, 23.2)

≥65 years
22.8%
(95% CI: 19.6, 26.3)

In total, 43% of people had a HbA_{1c} ≥8% and 20.1% had a HbA_{1c} ≥9%

SAGE study was a single-visit, cross-sectional, non-invasive analysis of data from 3858 adults from 17 countries aged 26 years and older with type 1 diabetes of at least a year's duration.

Renard E et al. Presented at EASD Annual Meeting September 17, 2019. Abstract OP 03.

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Pursuing glycaemic control in type 1 diabetes

People with type 1 diabetes can struggle with their glycaemic control

What are some of the **key challenges** they face in achieving glycaemic control?

Hypoglycaemia

Glycaemic variability

Treatment adherence

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Hypoglycaemia

Toujeo®
insulin glargine 300U/mL

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Hypoglycaemia has a major impact on patients' lives & diabetes management[1]

Regular non-severe hypoglycaemic episodes can cause

unawareness of hypoglycaemia[2]

Unawareness of hypoglycaemia significantly increases risk of

severe hypoglycaemia[2]

Experiencing severe hypoglycaemia can lead to

extreme fear of hypoglycaemia[1]

Fear of hypoglycaemia is a

barrier to glycaemic control[1]

The increased risk of severe hypoglycaemia through hypoglycaemia unawareness is life-threatening to people with type 1 diabetes[2]

1. Khunti K et al. Diabetes Res Clin Pract 2017;130:121-129. **2.** Szadkowska A, et al. Pediatr Endocrinol Diabetes Metab. 2018;3:126–134.

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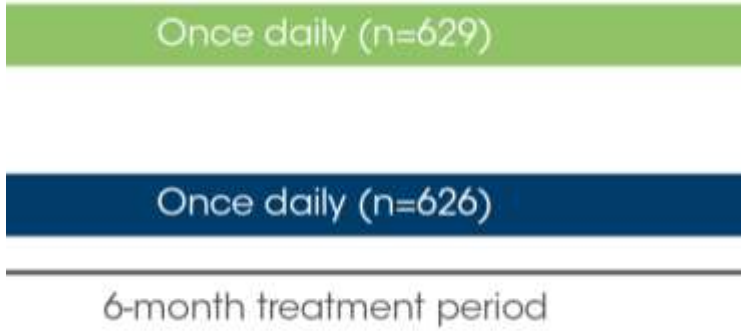
Post-hoc meta-analysis of three EDITION 6-month, Phase III, randomised clinical trials

Same study design



Primary endpoint of each of these studies was change in HbA_{1c} from baseline to week 26

Post-hoc meta-analysis aim:

Exploring the risk for severe hypoglycaemia with Toujeo® vs insulin glargine 100 units/mL in the pool of studied patients with T1DM

Limitations:

- The T1DM study pool consisted of heterogeneous populations that may, however, represent a large multi-national cohort of patients with T1DM eligible for Toujeo®
- The analysis was performed *post-hoc* and is exploratory in nature

Danne T, et al. Diabetes Obes Metab. 2020;22:1880–5.

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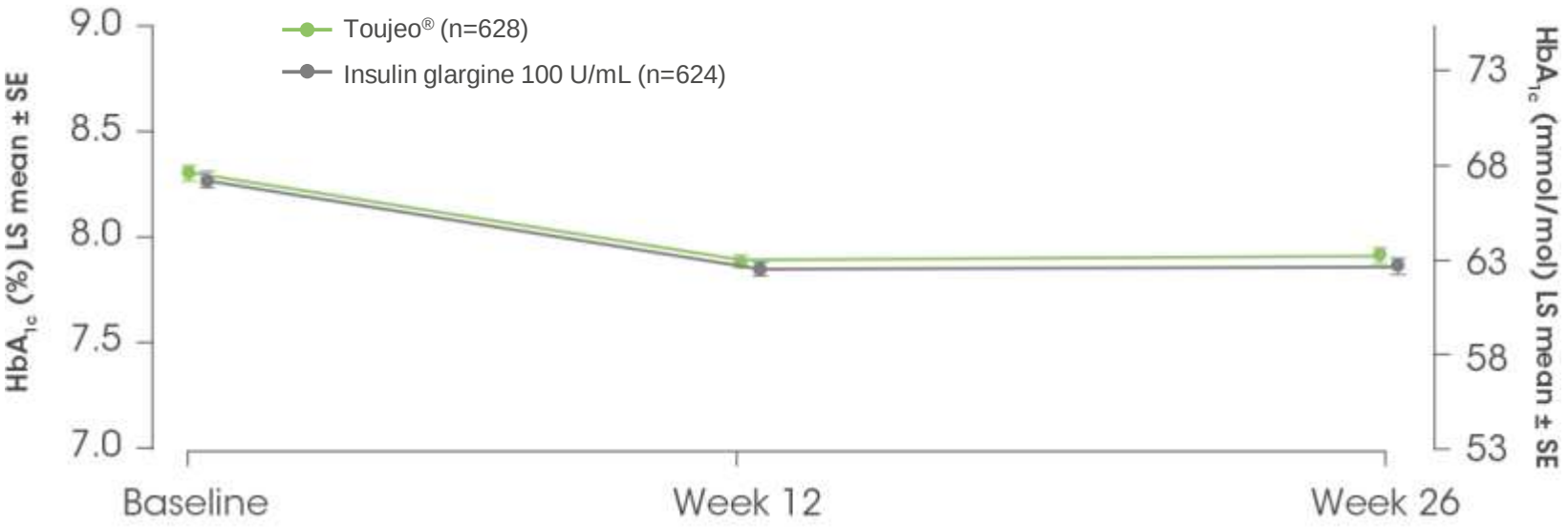
Comparable and effective HbA_{1c} reduction at 6 months with Toujeo® vs insulin glargine 100 units/mL

HbA_{1c} reduction from baseline to Month 6‡



HbA_{1c} LSM difference in the T1DM study pool from baseline to 6 months:

- Toujeo®, −0.38%
- Insulin glargine 100 units/mL, −0.44%
- RR (95% CI): 0.05 (−0.04 to 0.15)

Non-inferiority confirmed at the 0.3% margin

Adapted from Danne T, et al (2020)

The following T1DM patient populations that were pooled were EDITION 4 (n=549): adult patients (age ≥18 years), worldwide, EDITION JP 1 (n=243): adult patients (age ≥18 years), Japan and EDITION JUNIOR (n=463): children and adolescents (age 6–17 years), worldwide. The primary endpoint for each of the studies was non inferiority for HbA_{1c} reduction. All three trials had a similar design for regulatory purpose and achieved their primary endpoint of HbA_{1c} non inferiority of Toujeo® vs insulin glargine 100 units/mL.
‡Results are in the efficacy population (Toujeo®, n=628; insulin glargine 100 units/mL, n=624).
SE, standard error; LSM, least squares mean

Danne T, et al. Diabetes Obes Metab. 2020;22:1880–5.

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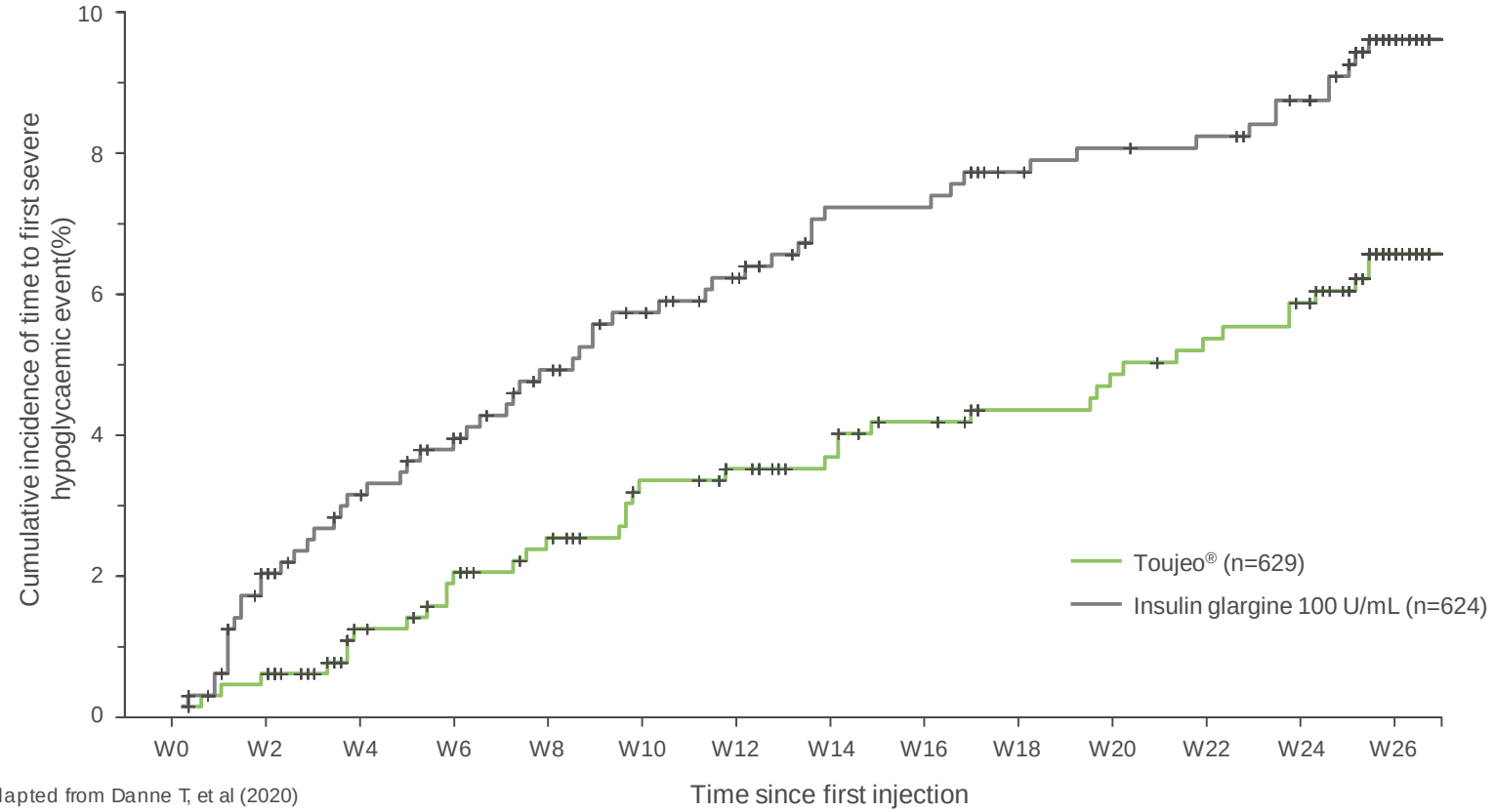
Lower risk of severe hypoglycaemia with Toujeo® vs glargine 100 U/mL

Post-hoc meta-analysis: EDITION 4, EDITION JP 1 and EDITION JUNIOR in T1DM has shown

Incidence of severe hypoglycaemia* from baseline to Month 6†



Adapted from Danne T, et al (2020)

*Severe hypoglycaemia was defined **in adults** as hypoglycaemic event that required assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions and **in children/adolescents** as an altered mental status and inability to assist in their care, being semiconscious or unconscious, or in coma — convulsions that may require parenteral therapy (glucagon and/or glucose). †Results are in the safety population (Toujeo®, n=629; Insulin glargine 100 U/mL, n=624). CI, confidence interval; T1DM, type 1 diabetes mellitus; W, week; M, month.

Danne T, et al. Diabetes Obes Metab. 2020;22:1880–5.

Severe hypoglycaemia*

Full study period (6 M)

Toujeo®, **6.2%**
Insulin glargine 100 U/mL, **9.3%**

Toujeo®
−35%

HR 0.65‡
(95% CI, 0.44-0.98)
p=0.038

‡Hazard ratio (HR) estimated using a Cox proportional hazard model with treatment group and study as fixed effects; log-rank test was stratified by study, and cumulative incidence curves were calculated using Kaplan–Meier estimates.

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Percentage of patients with ≥1 severe hypoglycaemia event with Toujeo® vs glargine 100 U/mL across the study periods

Post-hoc meta-analysis: EDITION 4, EDITION JP 1 and EDITION JUNIOR in T1DM has shown

Full study period (6 M)

Toujeo®, **6.2%**

Insulin glargine 100 U/mL, **9.3%**

Toujeo®

−35%

OR 0.65‡

(95% CI, 0.42-0.98)

p=0.042

Titration Period (First 8 weeks)

Toujeo®, **2.4%**

Insulin glargine 100 U/mL, **4.7%**

Toujeo®

−50%

OR 0.50

(95% CI, 0.27-0.95)

p=0.033

Maintenance Period (W9 to M6)

Toujeo®, **4.5%**

Insulin glargine 100 U/mL, **5.1%**

Toujeo®

−14%

OR 0.86

(95% CI, 0.51-1.45)

p=0.573

*Severe hypoglycaemia was defined **in adults** as hypoglycaemic event that required assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions and **in children/adolescents** as an altered mental status and inability to assist in their care, being semiconscious or unconscious, or in coma — convulsions that may require parenteral therapy (glucagon and/or glucose). †Results are in the safety population (Toujeo®, n=629; Insulin glargine 100 U/mL, n=624). ‡OR based on logistic model with treatment as fixed effect, and by adding study as fixed effect for the T1DM study pool; Cumulative incidences curves were calculated using Kaplan-Meier estimates. CI, confidence interval; OR, odds ratio; T1DM, type 1 diabetes mellitus; W, week; M, month.

Danne T, et al. Diabetes Obes Metab. 2020;22:1880–5.

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EDITION JUNIOR: Toujeo® vs insulin glargine 100 U/mL in T1DM

Objective

To demonstrate non-inferiority of Toujeo® vs insulin glargine 100 U/mL in change in HbA_{1c} from baseline to Week 26 in children/ adolescents with T1DM

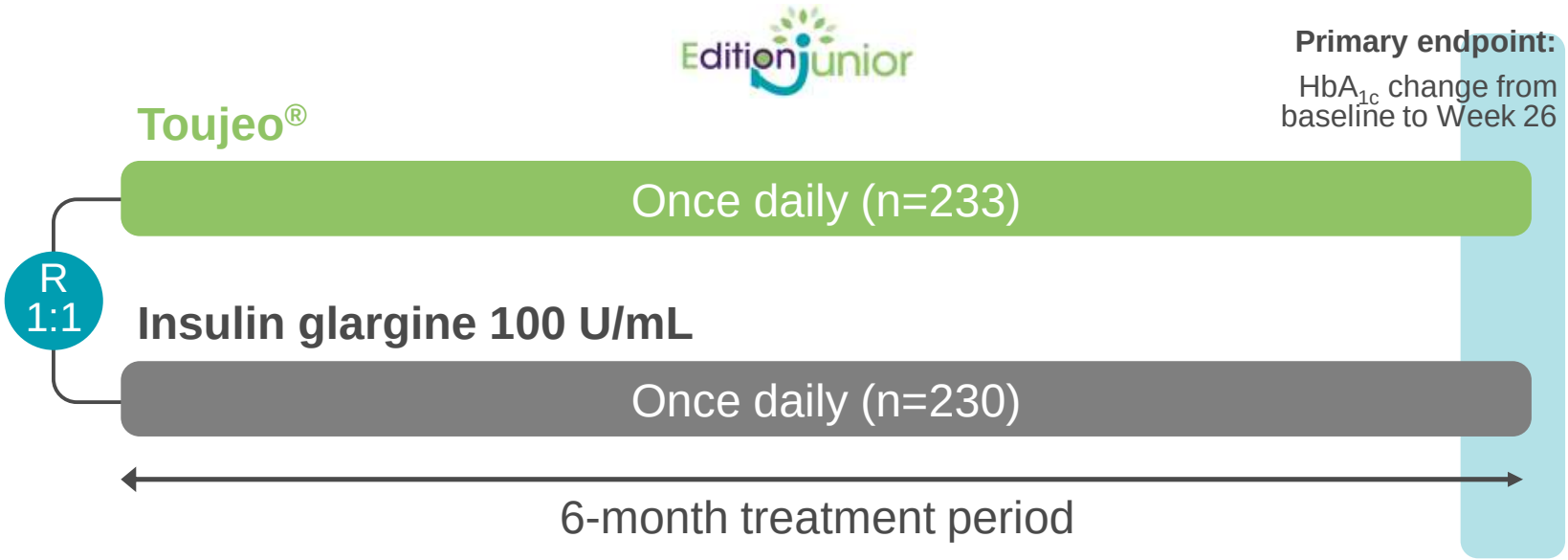
Study design

6-month, randomised, open-label, double-arm, parallel-group, non-inferiority study

Eligible patients:

- 6-17 years of age
- T1DM duration ≥1 year
- Previous basal insulin plus fast-acting insulin therapy
- HbA_{1c} ≥7.5% and ≤11%
- No premix insulins in ≤3months prior to screening

4 centres in the UK
Doncaster, Ipswich, Kettering, Salisbury



Primary endpoint

Change in HbA_{1c} from baseline to Week 26 (non-inferiority)

Selected secondary endpoints

- Hypoglycaemia events
- Hyperglycaemia events with ketosis (SMPG, ≥14 mmol/L and ketone ≥1.5 mmol/L)
- Treatment-emergent adverse events (TEAEs)

R, randomised; T1DM, type 1 diabetes mellitus; FPG, fasting plasma glucose; SMPG, self-monitored plasma glucose

Danne T et al. Diabetes Care 2020;43:1512-1519.

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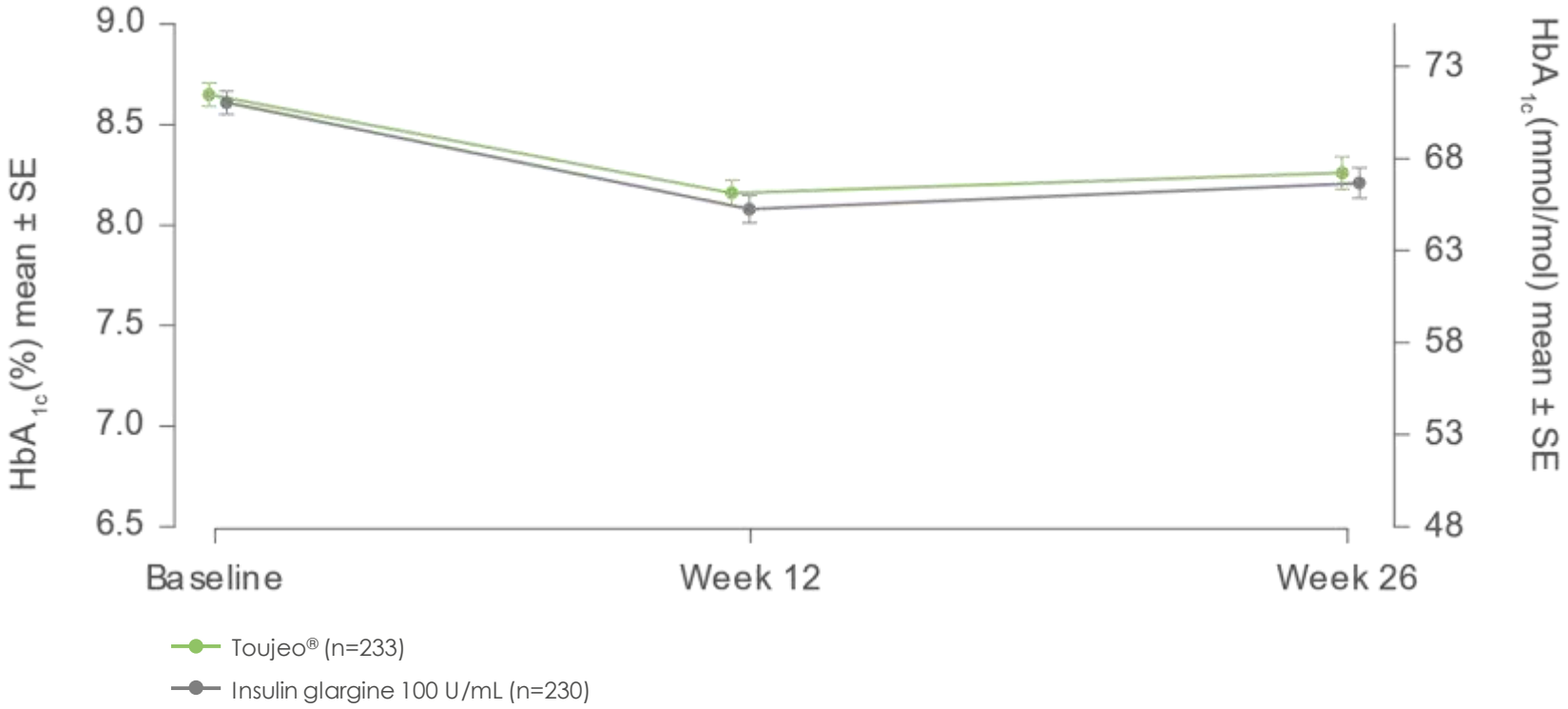
Comparable and effective HbA_{1c} reduction with Toujeo® vs insulin glargine 100 U/mL

Primary endpoint: Change in HbA_{1c} during the 26-week treatment period



CI, confidence interval; HbA1c, glycated haemoglobin; LSM, least squares mean; SE, standard error; T1DM, type 1 diabetes mellitus.
No safety issues were identified with respect to adverse events and standard safety parameters.

Danne T et al. Diabetes Care 2020;43:1512-1519.

Primary endpoint met

HbA_{1c} LSM reductions at Week 26

Baseline mean: 8.65%

Toujeo®
−0.4%
(95% CI: −0.17 to 0.18)

Baseline mean: 8.61%

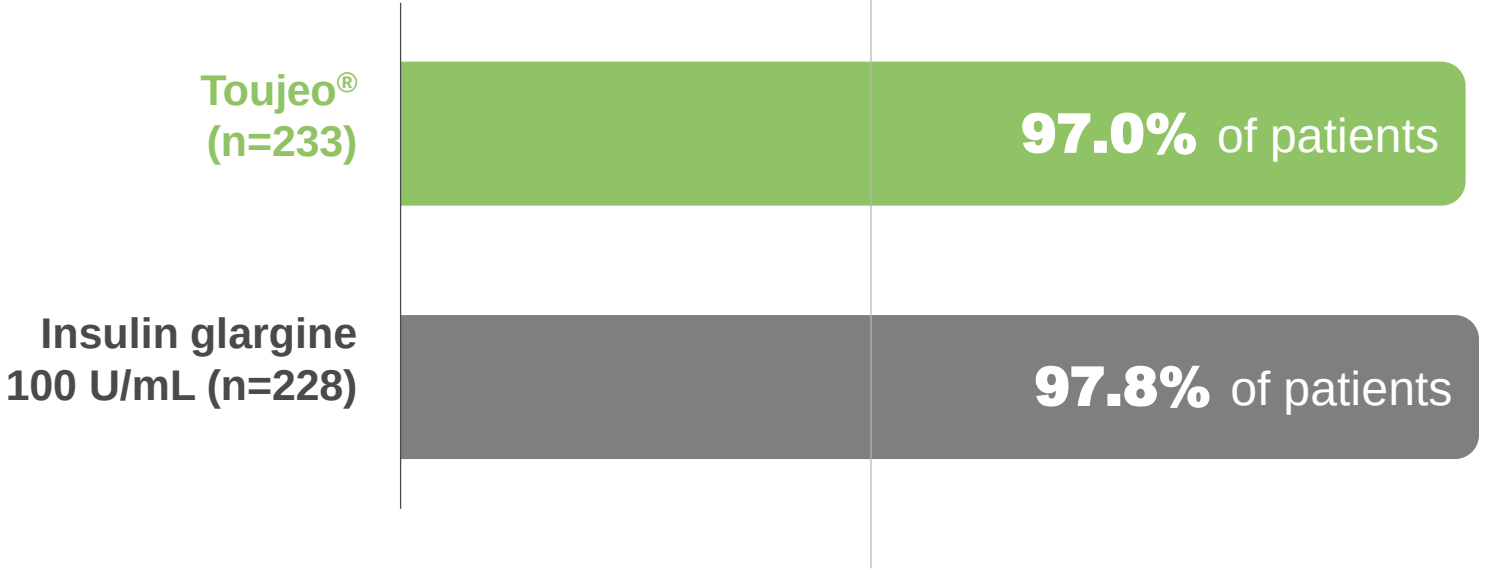
Glargine
−0.4%
(95% CI: −0.17 to 0.18)

LS mean between-group difference **0.004% (95% CI, −0.17 to 0.18)** confirming **non-inferiority** at the pre-specified 0.3% margin

Comparable overall hypoglycaemia with Toujeo® vs insulin glargine 100 U/mL

Incidence of hypoglycaemia during the 26-week treatment period

≥1 severe or documented (≤3.9 mmol/L]) event at any time of day during the main 6-month treatment period



*Safety population (Toujeo®, n=233; insulin glargine 100 U/mL , n=228). Corresponding event rates were comparable across both groups. Randomisation was stratified at screening by HbA1c (<8.5% and ≥8.5%) and by age (<12 years and ≥12 years), configured to ensure that ≥30% of participants would be <12 years of age. Percentage of patients with at least one event of hypoglycaemia according to different ADA and ISPAD-defined categories is shown in the table.

†Severe hypoglycaemia is defined as an event with altered mental status and cannot assist in their care, is semiconscious or unconscious, or in coma-convulsions and may require parenteral therapy (glucagon or glucose).

Danne T et al. Diabetes Care 2020;43:1512-1519.

Comparable overall hypoglycaemia with Toujeo® vs insulin glargine 100 U/mL

Incidence of hypoglycaemia during the 26-week treatment period

Hypoglycaemia category*	Toujeo® n=233	Insulin glargine 100 U/mL n=228	Relative risk (95% CI)
Anytime hypoglycaemia, severe† and/or documented			
<3.9 mmol/L	226 (97.0)	223 (97.8)	0.99 (0.96–1.02)
≤3.0 mmol/L	187 (80.3)	191 (83.8)	0.96 (0.88–1.04)
Nocturnal hypoglycaemia (00:00–05:59 h), severe† and/or documented			
<3.9 mmol/L	163 (70.0)	160 (70.2)	1.00 (0.88–1.12)
≤3.0 mmol/L	63 (27.0)	57 (25.0)	1.09 (0.80–1.47)

*Safety population (Toujeo®, n=233; insulin glargine 100 U/mL , n=228). Corresponding event rates were comparable across both groups. Randomisation was stratified at screening by HbA1c (<8.5% and ≥8.5%) and by age (<12 years and ≥12 years), configured to ensure that ≥30% of participants would be <12 years of age. Percentage of patients with at least one event of hypoglycaemia according to different ADA and ISPAD-defined categories is shown in the table.

†Severe hypoglycaemia is defined as an event with altered mental status and cannot assist in their care, is semiconscious or unconscious, or in coma-convulsions and may require parenteral therapy (glucagon or glucose).

Danne T et al. Diabetes Care 2020;43:1512-1519.

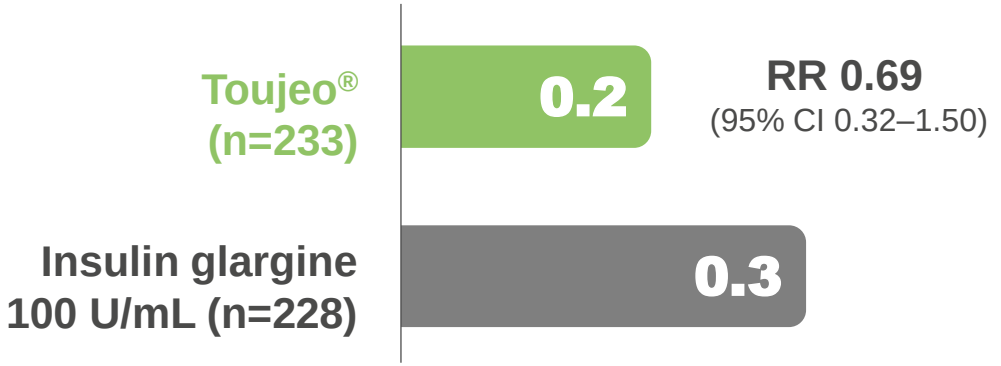
Numerically lower incidence & event rate of severe hypoglycaemia with Toujeo® vs insulin glargine 100 U/mL

Severe hypoglycaemia during the 26-week treatment period*

Event with altered mental status and inability to self-care, is semiconscious or unconscious, or in a coma with or without convulsions, who may require parenteral therapy

Incidence at any time of day

Event rate at any time of day (event/participant-year)



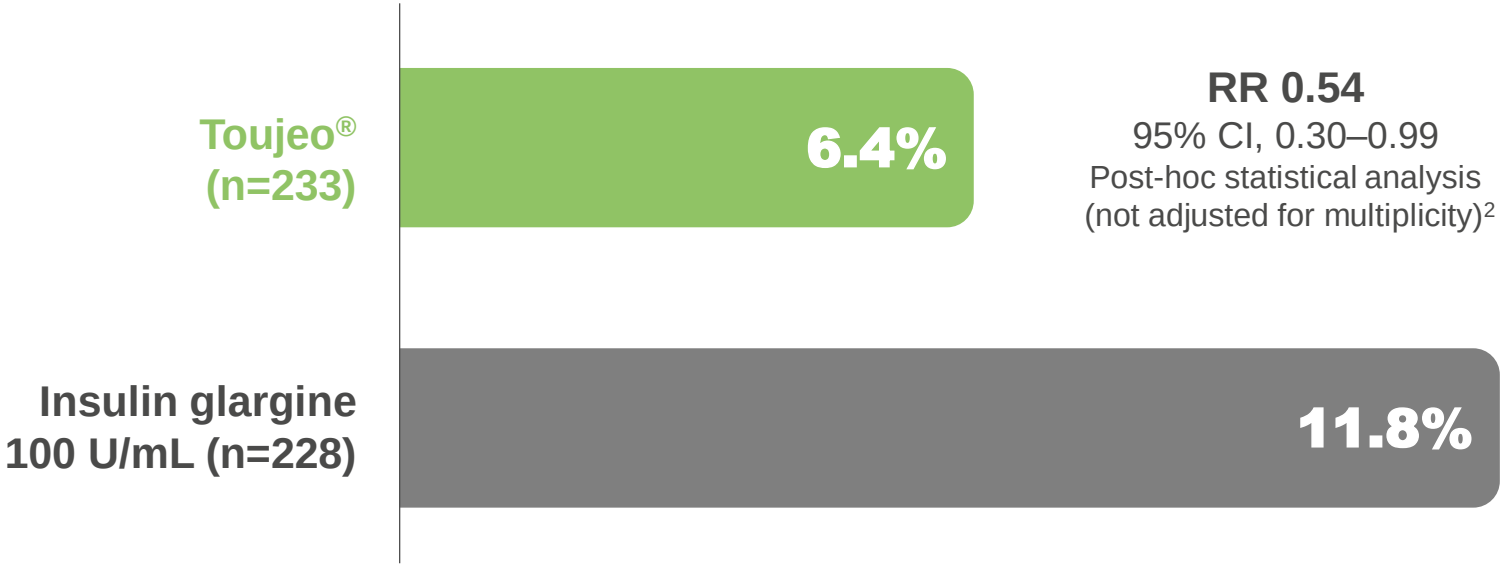
*Safety population (Toujeo®, n=233; insulin glargine 100 U/mL , n=228). Randomisation was stratified at screening by HbA1c (<8.5% and ≥8.5%) and by age (<12 years and ≥12 years), configured to ensure that ≥30% of participants would be <12 years of age.

CI, confidence interval; RR, relative risk

Danne T et al. Diabetes Care 2020;43:1512-1519.

Lower incidence of hyperglycaemia with ketosis with Toujeo® vs insulin glargine 100 U/mL*

Incidence of ≥1 TEAE of hyperglycaemia with ketosis†[1]



Future studies sufficiently powered to detect potential differences between these basal insulin analogues would be of interest to explore whether Toujeo® may provide a suitable therapy option in individuals at high risk of hyperglycaemia and ketosis

*Numerically lower rate of hyperglycaemia with ketosis with Toujeo® vs Lantus® at 26 weeks: 0.30 vs 0.41 rate per patient-year, RR (95% CI): 0.56 (0.26–1.21);[2] >50% of all documented ketone values ≥1.5 mmol/L were reported by two patients.[1]

†Safety population (Toujeo®, n=233; insulin glargine 100 U/mL , n=228). Randomisation was stratified at screening by HbA1c (<8.5% and ≥8.5%) and by age (<12 years and ≥12 years), configured to ensure that ≥30% of participants would be <12 years of age. *Ketones were measured when: SMPG was ≥14 mmol/L in an unwell child; or when SMPG remained ≥14 mmol/L without substantial decline; 60–120 min after an additional dose of rapid-acting insulin; or during illness with fever or vomiting, irrespective of the SMPG value.

CI, confidence interval; RR, relative risk; TEAE, treatment-emergent adverse event

1. Danne T et al. Diabetes Care 2020;43:1512-1519. **2.** Sanofi Data on File. SAGB.TJO.20.03.0549

Glycaemic variability

Toujeo®
insulin glargine 300U/mL

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The problem of glycaemic variability in people with type 1 diabetes

Frequent or large fluctuations in blood glucose levels may contribute to diabetes-related complications[1]

~56%

of T1DM patients were found to have excess glycaemic variability*[2]

8.5h/day

spent out of range for an average patient with T1DM[3]**

↓QoL

Excess glycaemic variability can negatively impact patients' quality of life[4]

*122 persons with T1DM underwent CGM at the University Hospital of Montpellier. Excess glucose variability defined as percentage coefficient of variation for glucose (%CV) >36%.
%CV = [(SD of glucose)/(mean glucose)] × 100) **Time in range is defined as the percentage of readings in the range of 70–180 mg/dL (3.9–10.0 mmol/L) per unit of time.[1]

%CV, percentage coefficient of variation; CGM, continuous glucose monitor; QoL, quality of life; T1DM, Type 1 diabetes mellitus

1. Danne T, et al. Diabetes Care. 2017; 40:1631–1640. 2. Monnier L, et al. Diabetes Care. 2017;40:832–838. **3.**Agiostratidou G, et al. Diabetes Care. 2017;40:1622–1630. 4. Ayano-Takahara S et al. Diabetes Care 2015 Jan; 38(1): e1-e2.

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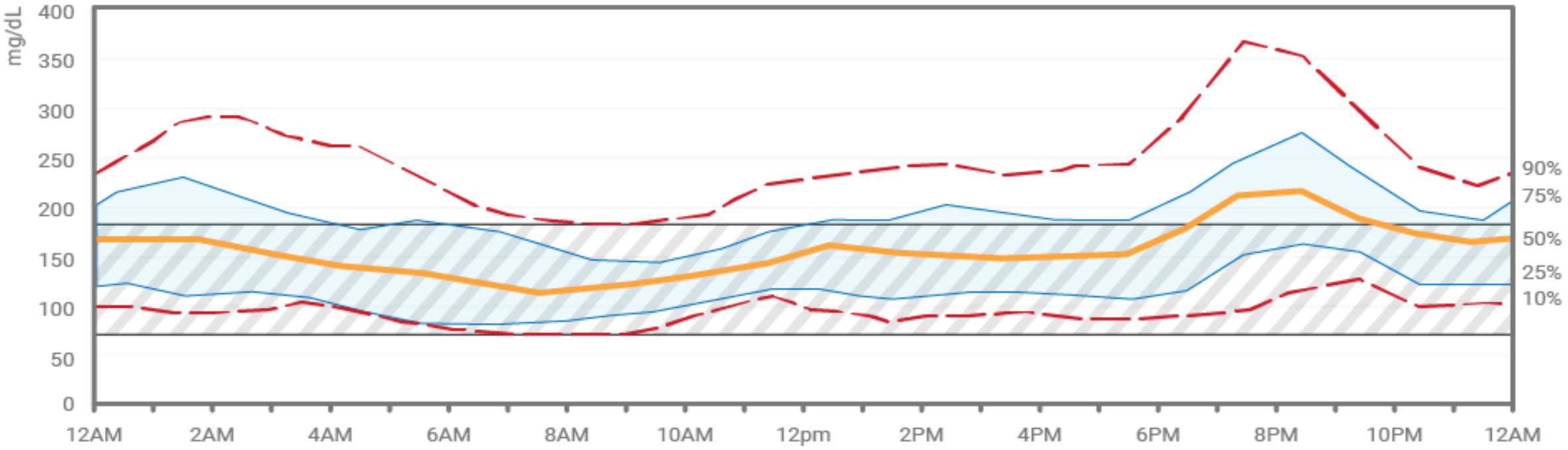
Ambulatory glucose profile reveals wide glycaemic variability in T1DM

Jonas (age 68) with laboratory measured HbA_{1c} = 8%



50%-Median | 25/75%-IQR | 10/90% | Target Range | Time in range = **63.8%**

Reference ranges calculated from population without diabetes. Curves/plots represent glucose frequency distributions by time regardless of date. Please note, case studies do not show real patients. They may not represent the wider patient population and the experiences of individual patients may vary.
CGM, continuous glucose monitor; IQR, interquartile range; T1DM, Type 1 diabetes mellitus

Beck R, et al. Diabetes Care. 2017;40:994–999.

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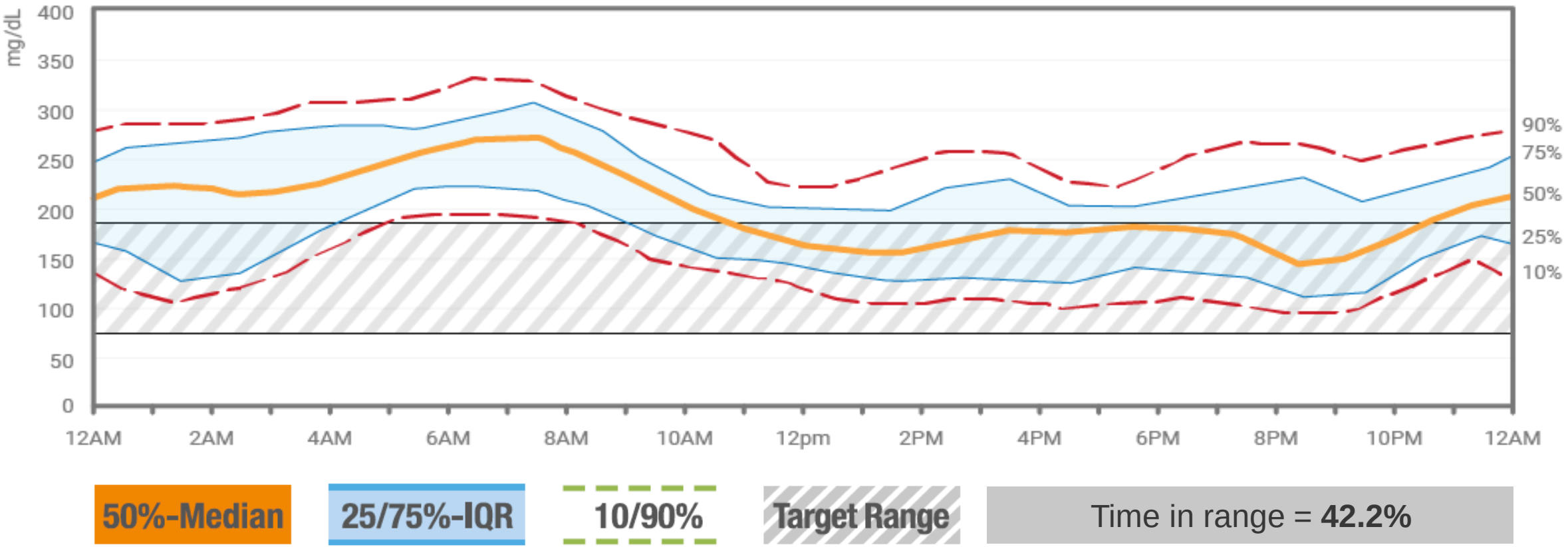
Ambulatory glucose profile reveals wide glycaemic variability in T1DM

Alicia (age 24) with laboratory measured HbA_{1c} = 8%



Reference ranges calculated from population without diabetes. Curves/plots represent glucose frequency distributions by time regardless of date. Please note, case studies do not show real patients. They may not represent the wider patient population and the experiences of individual patients may vary.
CGM, continuous glucose monitor; IQR, interquartile range; T1DM, Type 1 diabetes mellitus

Beck R, et al. Diabetes Care. 2017;40:994–999.

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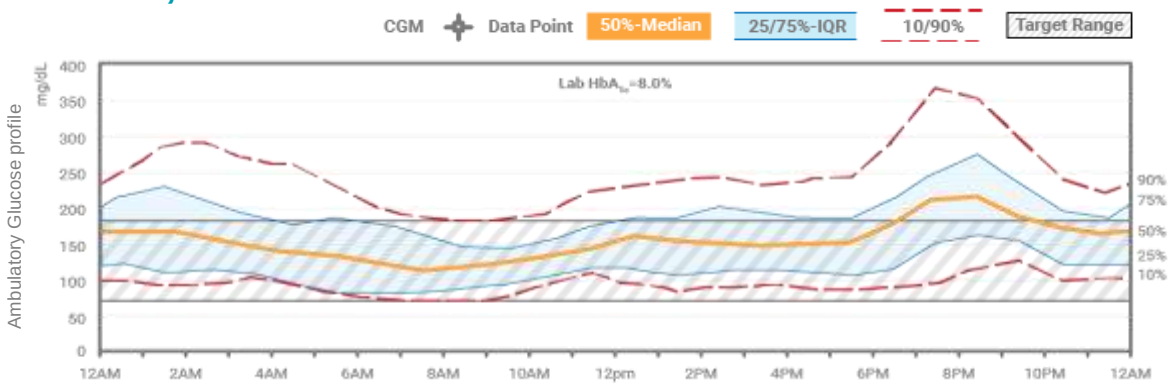
CGM—clinical data specific to the patient to determine optimal treatment

Lab-measured HbA_{1c}

8.0%

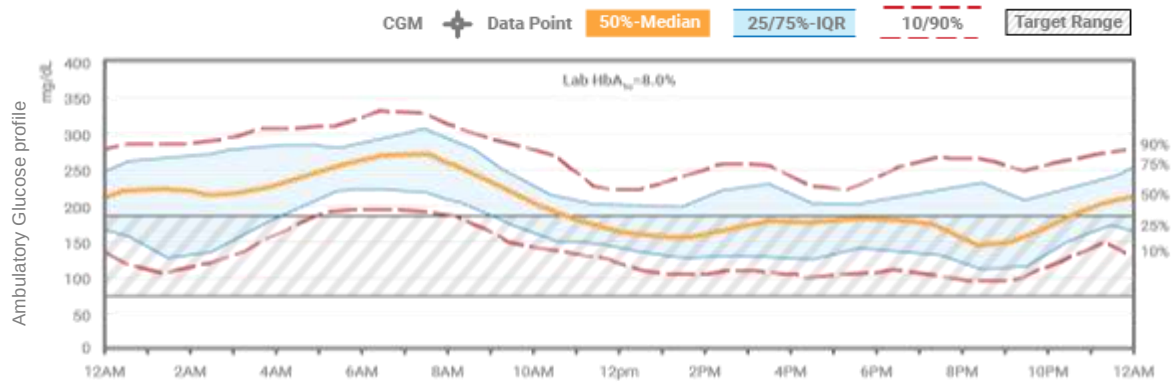
Jonas, 68



Mean glucose
9.1 mmol/L*†
Estimated HbA_{1c}: **7.3%**

In-target range (70–180 mg/dL)*
63.8%

Alicia, 24



Mean glucose
10.8 mmol/L*
Estimated HbA_{1c}: **8.4%**

In-target range (70–180 mg/dL)*
42.2%

Assessing a patient's glucose profile and glycaemic variability has considerable value for optimising their diabetes management

*Reference ranges calculated from population without diabetes; †Mean glucose reading in population without diabetes 88–116 mg/dL.
Curves/plots represent glucose frequency distributions by time regardless of date. Please note, case studies do not show real patients. They may not represent the wider patient population and the experiences of individual patients may vary.
CGM, continuous glucose monitor; IQR, interquartile range; T1DM, Type 1 diabetes mellitus

Beck R, et al. Diabetes Care. 2017;40:994–999.

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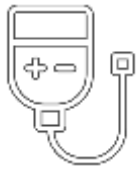
Glycaemic stability of Toujeo® vs insulin glargine 100 U/mL and degludec 100 U/mL

Activity profile vs insulin glargine 100 U/mL

PK/PD data

Becker RH
30 patients with T1DM[1]

Porcellati F
18 patients with T1DM[2]



CGM data

Bergenstal R
59 patients with T1DM[3]

Pettus J
104 patients with T1DM [6]

Activity profile vs insulin degludec 100 U/mL

PK/PD data

Bailey TS
48 patients with T1DM[4]

Lucidi P
22 patients with T1DM[5]

CGM studies

InRange
338 patients with T1DM [7]

Ongoing study

The clinical implications of PK/PD data require further evaluation including CGM studies and larger clinical studies.

1. Becker R et al. Diabetes Care 2015;38:637–643. **2.** Porcellati F, et al. Diabetes Care 2019;42:85-92. **3.** Bergenstal RM, et al. Diabetes Care 2017;40:554-560. **4.** Bailey TS, et al. Diabetes Metab. 2018;44:15–21. **5.** Lucidi P et al. Diabetes care 2020 **6.** Pettus J, et al. Diabetes Obes Metab 2019;21:1906-13 **7.** Battelino t, et al. Diabetes Ther 2020;11:1017–1027.

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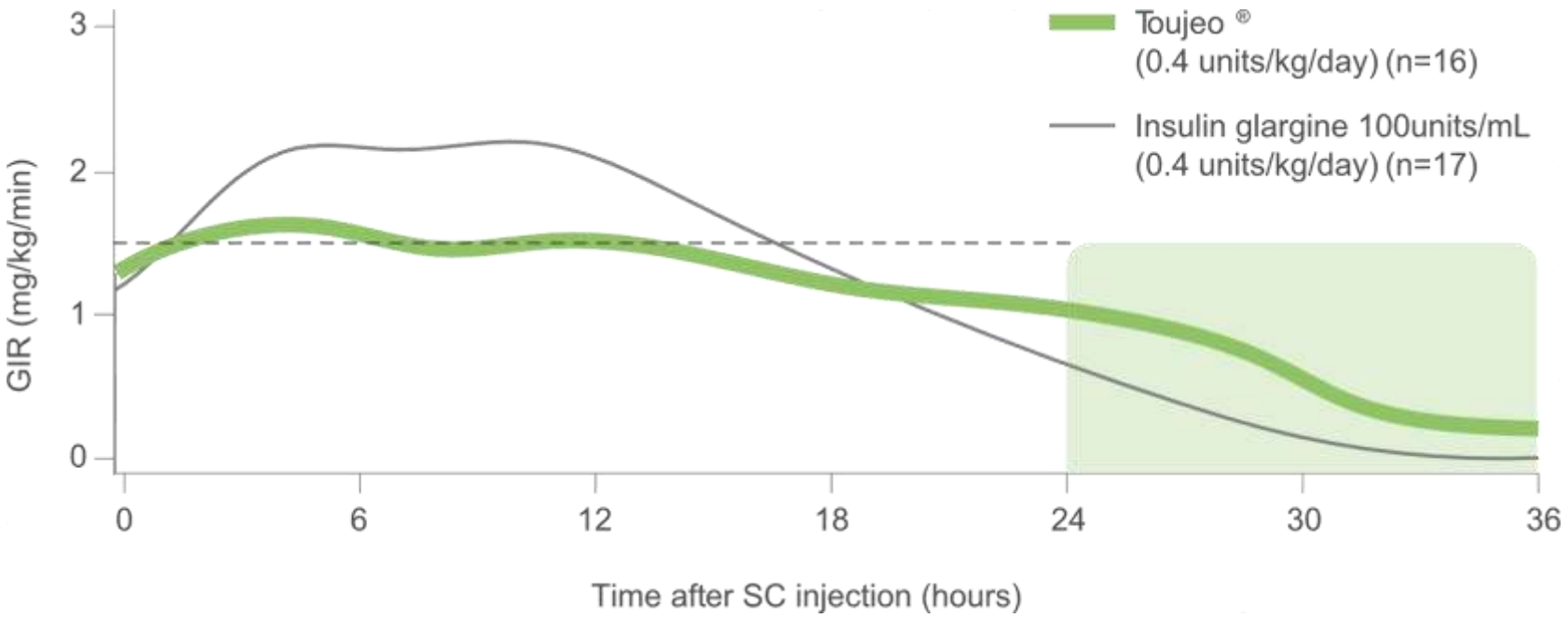
Toujeo® is associated with a more stable & prolonged activity profile than insulin glargine 100 U/mL

Activity profile at steady state in T1DM patients[1]



Toujeo® has a

flatter, more stable

activity profile extending beyond 24 hours[2]

The clinical implications of PK/PD data require further evaluation including CGM studies and larger clinical studies

The results of euglycaemic clamp studies do not necessarily predict clinical outcomes in all patients

CGM, continous glucose monitoring; GIR, glucose infusion rate; LOESS, locally weighted scatter plot smoother; PD, pharmacodynamic; PK, pharmacokinetic; SC, subcutaneous; T1DM, type 1 diabetes mellitus.

1. Becker R et al. Diabetes Care 2015;38:637–643. 2. Toujeo® Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/6938/smpc [Accessed December 2022].

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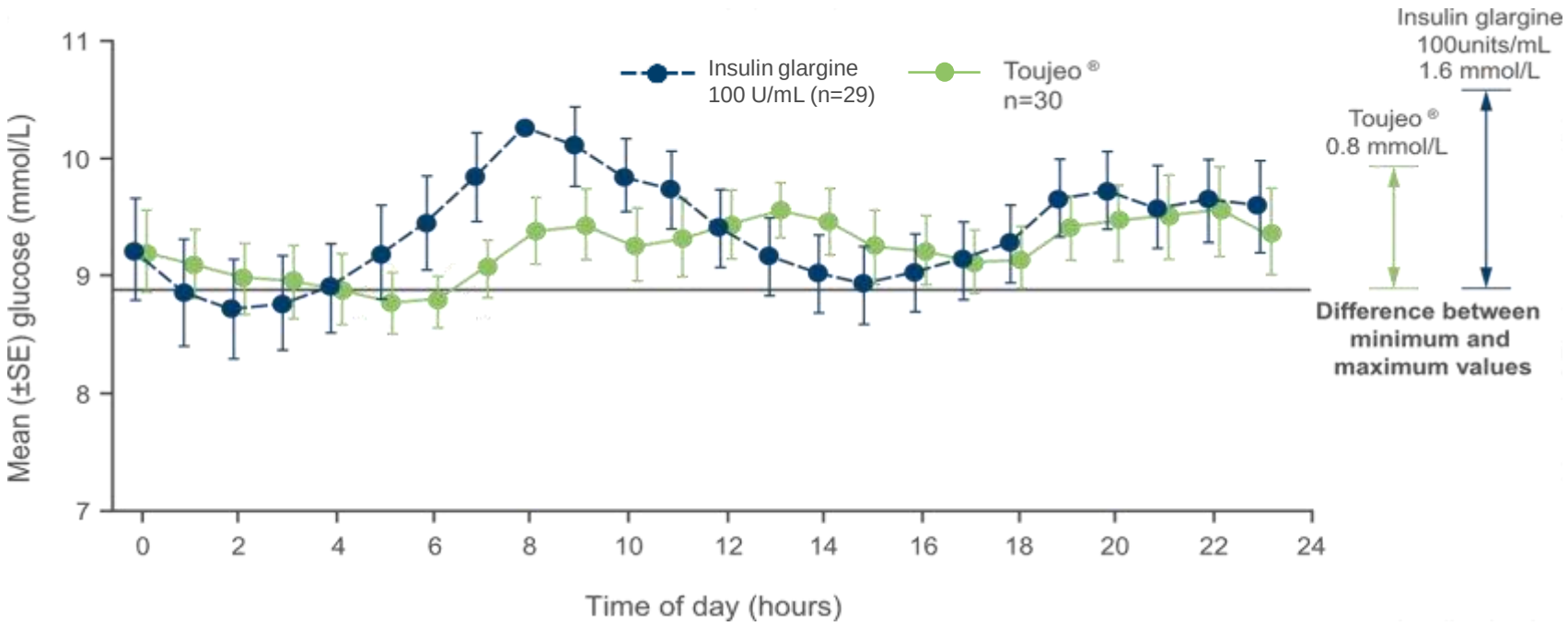
Toujeo® is associated with less within-day glucose fluctuation than insulin glargine 100 U/mL

16-week, exploratory, open-label, parallel-group, two-period crossover study in 59 adults with T1DM

Average glucose profiles evaluated in T1DM patients with CGM



Lower within-day fluctuation

Toujeo®

−50%

vs insulin glargine 100 U/mL

Primary endpoint:

The percentage of time within the target glucose range was comparable between the Gla-300 and Gla-100 groups.

Adapted from Bergenstal R, et al. 2017.

CGM, continuous glucose monitoring; SE, standard error; SMPG, self-measured plasma glucose; T1DM, type 1 diabetes mellitus. Mean glucose profile over 24 hours during the last two weeks of treatment (following 6 weeks of dose adjustment) for Toujeo® vs Insulin glargine 100 U/mL overall. Data displayed are mean hourly glucose values by time of day, pooled across all participants within each treatment group (Toujeo® and Insulin glargine 100 U/mL) and time of administration (morning and evening). The horizontal black line represents the postprandial SMPG target used within this study (8.9 mmol/L).

Bergenstal RM, et al. Diabetes Care 2017;40:554-560.

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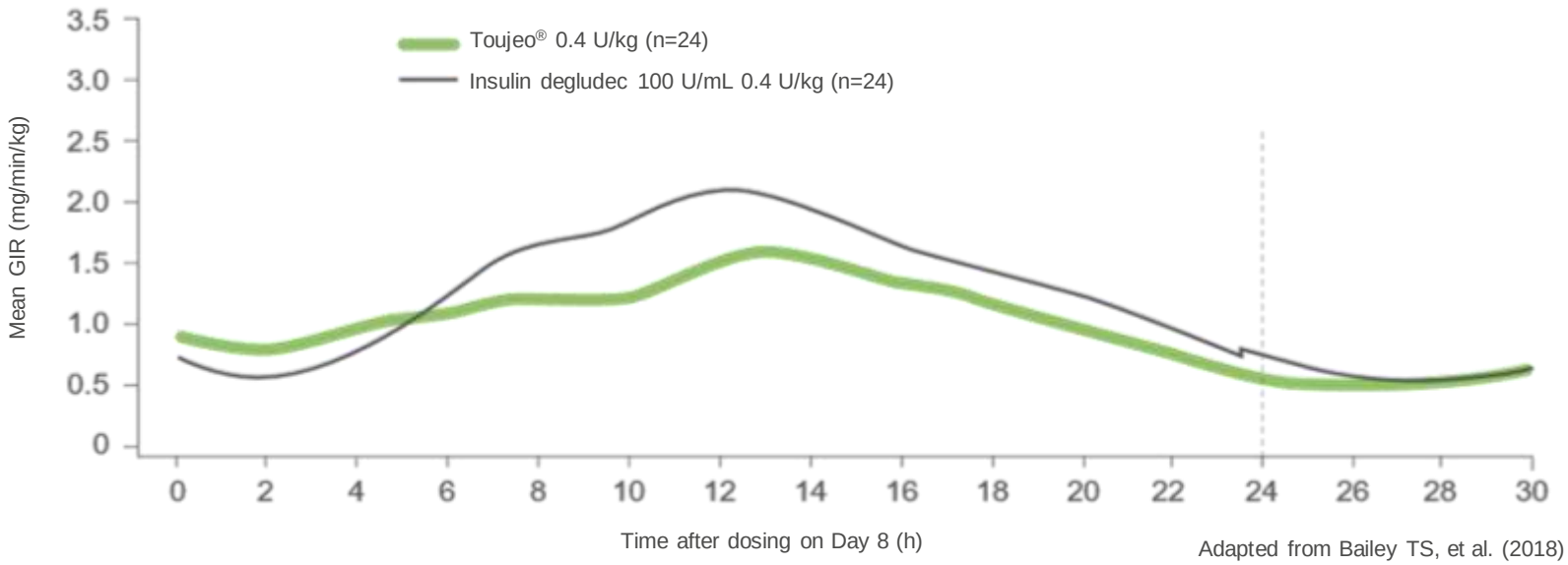
Less within-day fluctuation with Toujeo® vs insulin degludec 100 U/mL

GIR profiles at a 0.4 U/kg/day dose level in steady state*[1]



Adapted from Bailey TS, et al. (2018)

Primary endpoint:
Mean GIR-smFL$_{0–24}$, was significantly lower with Toujeo® (mean of 0.38 mg/min/kg) vs degludec 100 U/mL mean of (0.46 mg/min/kg) at the 0.4 U/kg/day dose level (treatment ratio: 0.80 [90% CI: 0.66 to 0.96]; p=0.047).
Mean GIR-smFL$_{0–24}$, was numerically lower with Toujeo® (0.45 mg/min/kg) than with degludec 100 U/mL (0.48 mg/min/kg) at the 0.6 U/kg/day dose level (treatment ratio: 0.96 [90% CI: 0.83 to 1.11]; p=0.603).

Primary endpoint:
fluctuation of smoothed GIR curve over 24-hour dosing period in steady state.

Lower within-day fluctuation

Toujeo®

−20%

Toujeo vs degludec 100 U/mL
(mean GIR-smFL$_{0–24}$)
Treatment ratio: 0.80
(90% CI: 0.66 to 0.96)
p=0.047

The clinical implications of PK/PD data require further evaluation including CGM studies and larger clinical studies

The results of euglycaemic clamp studies do not necessarily predict clinical outcomes in all patients

Bailey TS, et al. Diabetes Metab. 2018;44:155–21

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The first H2H RCT comparing Toujeo® vs insulin degludec 100 U/mL in T1DM

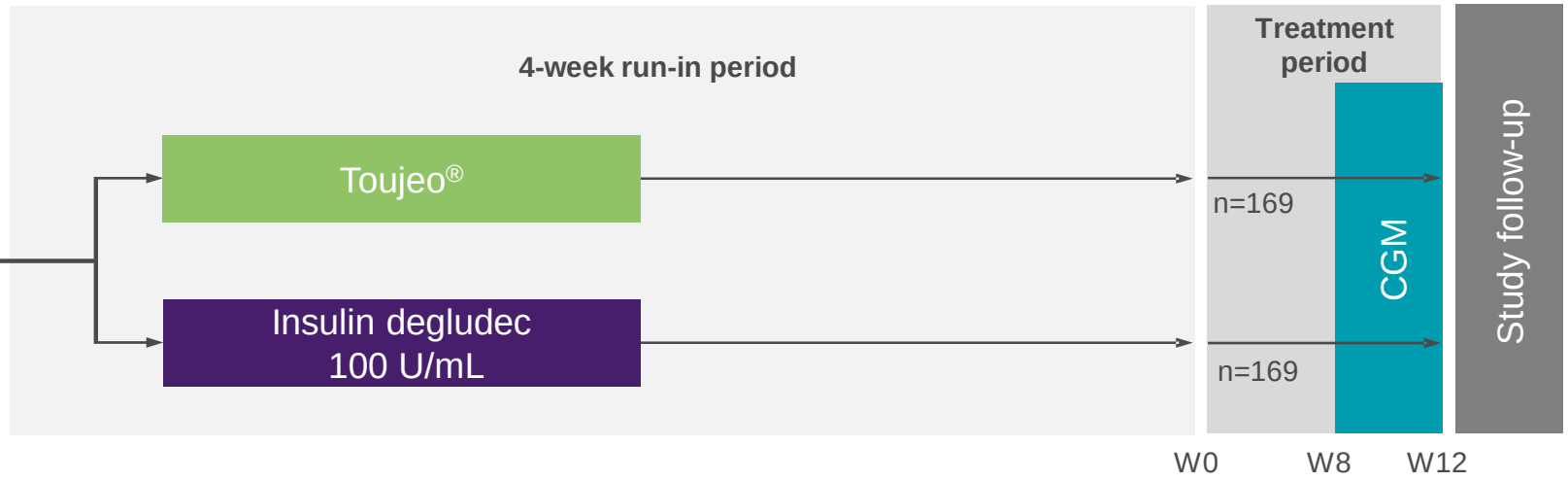
Objective

To demonstrate non-inferiority of Toujeo® vs insulin degludec 100 U/mL in the percentage of time in range (TIR) (3.9–10 mmol/L) in adults with T1DM

Study design

Multicentre, randomised, active-controlled, parallel-group, 12-week, open-label, phase 4 study will collect CGM data over 20 consecutive days from adults with T1D randomised to receive Gla-300 or IDeg-100

- Adults with T1D aged 18—70
- HbA_{1c} ≥7% to <10%
- Any once-daily basal insulin and rapid acting analogues for at least 1 year
- No Toujeo or insulin degludec 100 U/mL in the last 30 days
- NCT04075513



H2H, head-to-head; RCT, randomised controlled trial; T1DM, Type 1 diabetes mellitus; W, week; CGM, continuous glucose monitoring

Battelino T, et al. Diabetes Ther 2020;11:1017–1027

Flexibility and support

Toujeo®
insulin glargine 300U/mL

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Toujeo®: once-daily dosing with flexible injection time when needed

Once daily injection

Prolonged activity profile

Toujeo® can give your patients sustained glycaemic control when administered once daily in the **morning or evening***[1]

Flexible injection time when needed

6-hour window[1]

Toujeo® can give your patients **flexibility** around their injection time to fit in with their daily lives when needed*†[1]

*Observed in clinical studies conducted in adults †The dose regimen (dose and timing) should be adjusted according to individual response

1. Toujeo® Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/6938/smpc [Accessed December 2022].

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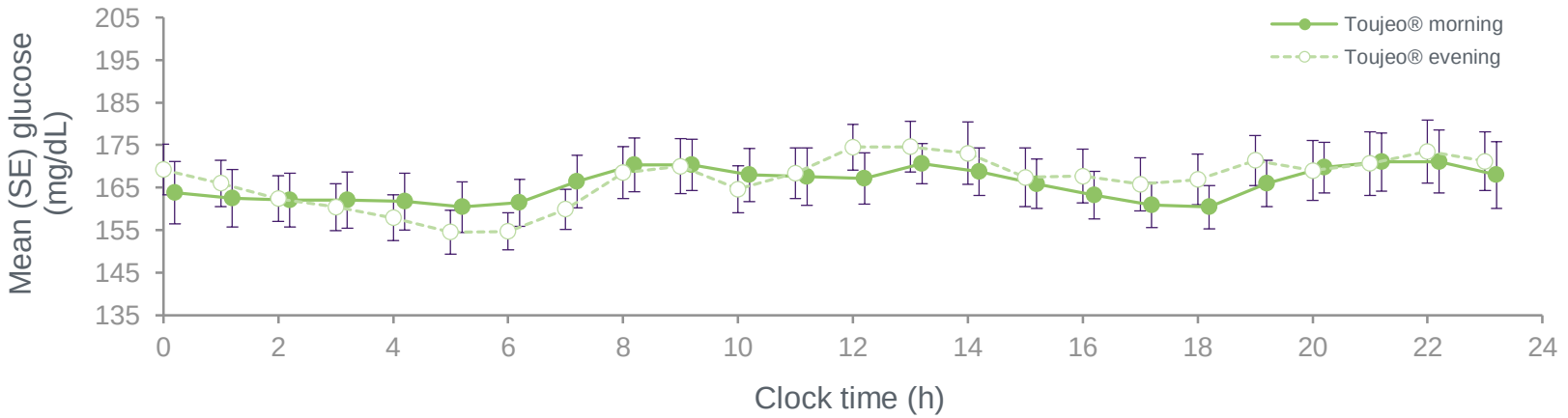
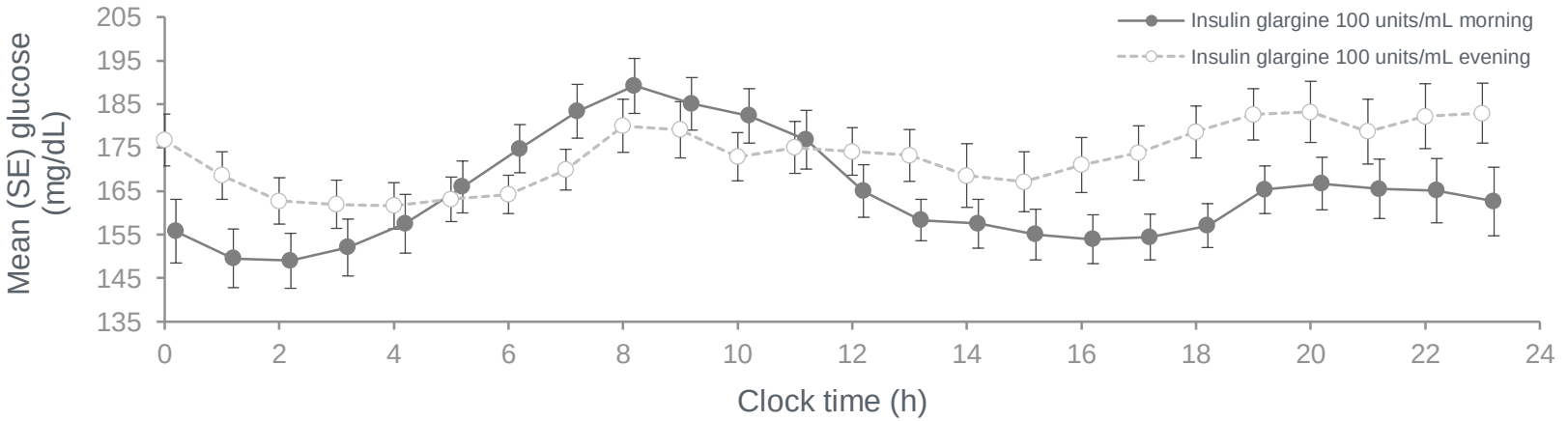
Toujeo® 24-hour glucose profiles supports once daily injection in morning/evening

Mean 24-hour glucose profiles (last 2 weeks of treatment by injection schedule)

Toujeo® (n=30)



Insulin glargine 100 U/mL (n=29)



Bergenstal RM, et al. Diabetes Care 2017;40:554-560.

Toujeo® has a

smaller difference in glucose level throughout the day irrespective of a morning or evening injection

versus insulin glargine 100 U/mL

Mean morning injection time (approximately 8am)

Mean evening injection time (approximately 8pm)

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How to start or switch to Toujeo® in your patients with type 1 diabetes

Toujeo® is used once-daily with meal-time insulin and requires individual dose adjustments

- Determine your patient's **starting dose**
- **Toujeo®** must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements

- **Switching from insulin glargine 100 units/mL**
  - **Unit-to-unit conversion** but a higher **Toujeo®** dose may be needed to achieve target plasma glucose levels

- **Switching from other basal insulins**
  - **Once daily long-acting insulins:** unit-to-unit conversion
  - **Twice daily basal insulins:** Initial **Toujeo®** dose 80% of previous total basal insulin dose
  - **Close metabolic monitoring** is recommended during the switch and in the initial weeks thereafter

- Units of Toujeo® are rounded down to the nearest whole unit
- For example, 41 units x 80% = 32 units

Before prescribing the product, always refer to the Summary of Product Characteristics

Toujeo Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/6938/smpc [Accessed December 2022].

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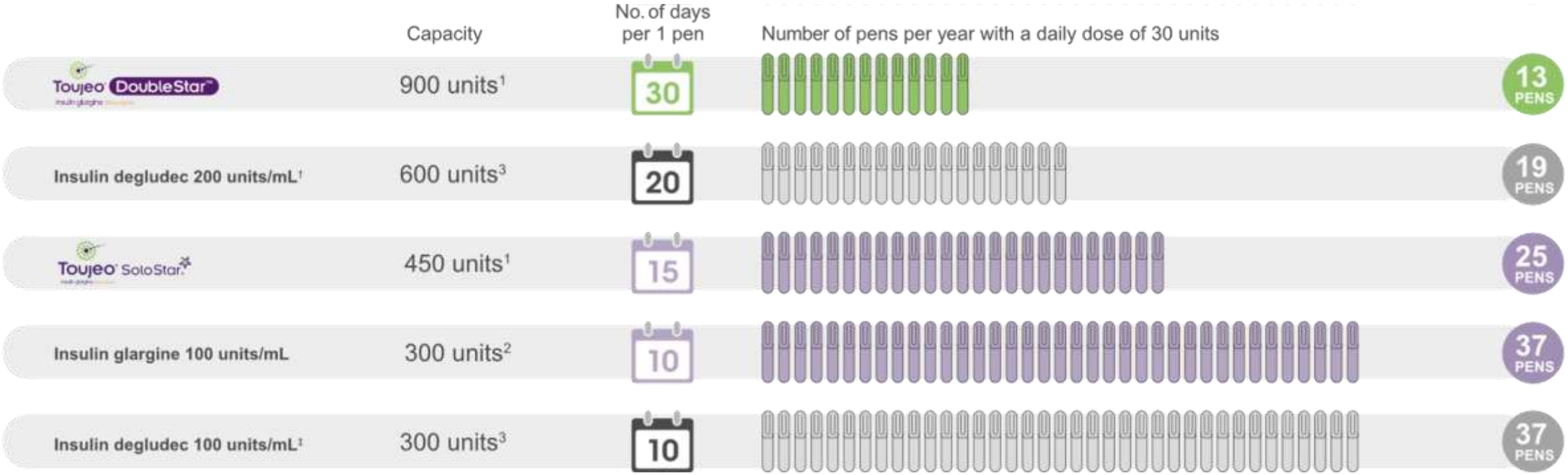
Toujeo® DoubleStar—the highest unit capacity basal insulin pen on the market[1-5]

Offering convenience for your patients with a long-lasting pen*



*For patients who require a dose of >80 U/day and who need to split their dose, Toujeo® DoubleStar can offer fewer injections which can add convenience
†Tresiba FlexTouch units-200
‡Tresiba FlexTouch units-100

This information is based on daily unit consumption only, and does not take into account any differences in clinical efficacy between the insulins compared.

Toujeo® DoubleStar® is recommended for appropriate patients with diabetes mellitus who require at least 20 units of basal insulin per day.
*For patients who require a dose of >80 units per day and who need to split their dose, Toujeo® DoubleStar® can offer fewer injections which can add convenience.

1. Toujeo Summary of Product Characteristics. Available at https://www.medicines.org.uk/emc/product/6938/smpc [Accessed December 2022]. **2.** Lantus Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/2376/smpc [Accessed December 2022]. **3.** Tresiba Summary of Product Characteristics. Available at https://www.medicines.org.uk/emc/product/2944/smpc [Accessed December 2022]. **4.** Levemir Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/5536/smpc [Accessed December 2022]. **5.** Singh R, et al. Eur Endocrinol. 2018;14;47–51.

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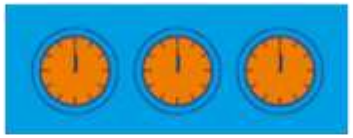
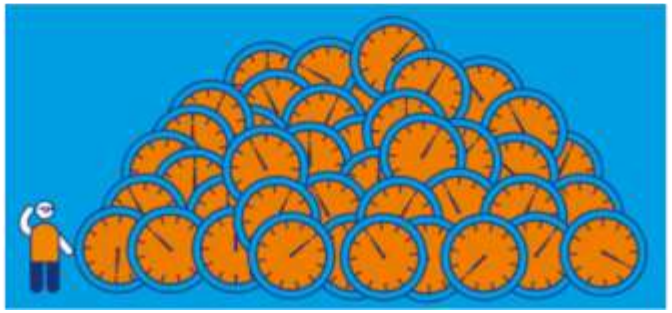
Managing Diabetes

2019

People with diabetes spend around **3 hours** with a healthcare professional every year[1]



For the remaining **8,757 hours** they must manage their diabetes themselves[1]



2020 COVID-19 pandemic

Need for increased use of **remote consultations** in order to reduce the face-to-face contact[2]

Patients find **harder to manage** their diabetes and to **access help and advice**[3]

Emotional and behavioral changes are increasing for people with diabetes in response to a crisis[4]

1. Diabetes UK. Us, diabetes and a lot of facts and stats_ January 2019. 2. Royal Collage of Nursing. Remote Consultations Guidance Under COVID-19 Restrictions. May 2020; 3. Diabetes UK. Position statement (August 2020) Availability of specialist support and equal access to surgery for people with diabetes; 4 Dubey S et al. DMSCRR 2020; 14:779-88

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Dedicated websites to support people who have been prescribed Toujeo®

Simply share the link or the QR code below with people who have been prescribed Toujeo®. They allow easily access to resources and support which will help them have the best experience with the product.

Toujeo® SoloStar®

https://www.mysanofiinsulin.co.uk/toujeosolostar/

Toujeo® DoubleStar™

insulin glargine

https://www.mysanofiinsulin.co.uk/toujeodoublestar/

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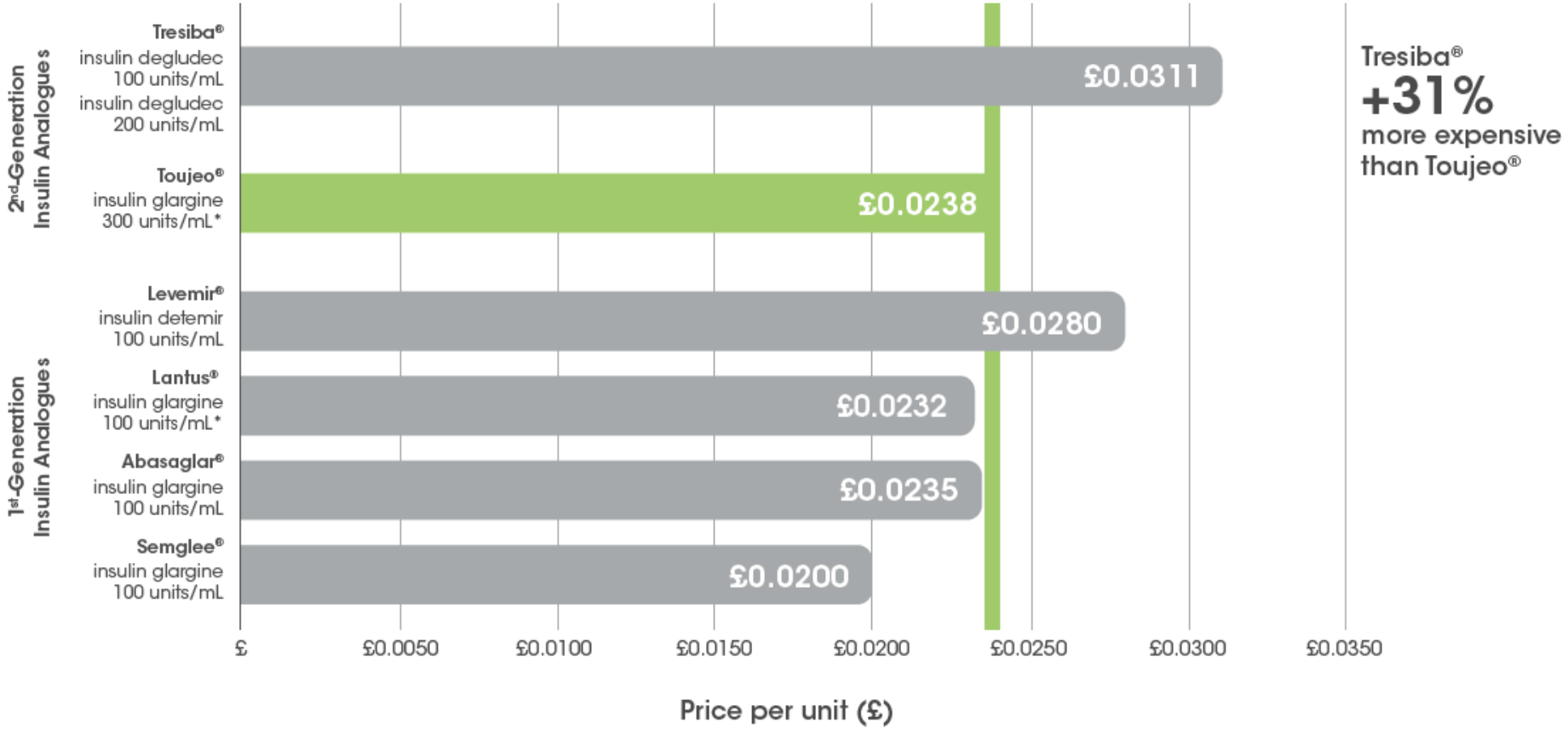
Long-acting insulin acquisition costs—price per unit[1-3]

These insulins are **not** bioequivalent and costs are **not** based on dose-for-dose comparisons*



***Insulin glargine 100 units/mL and Toujeo® are not bioequivalent, a higher dose of Toujeo® (~10–18%) may be needed to achieve target ranges for plasma glucose levels, as shown in the treat-to-target randomised controlled trials[2]. In the treat-to-target BRIGHT trial, at Week 24 Toujeo® insulin dose was higher by 0.11 units/kg than degludec 100 units/mL dose[3].**

References: 1. MIMS January 2021. Available at: https://www.mims.co.uk/. [Accessed: December 2022]. 2. Toujeo® Summary of Product Characteristics. Available athttps://www.medicines.org.uk/emc/product/6938/smpc [Accessed: December 2022]. 3. Rosenstock J, *et al. Diabetes Care.* 2018;41:2147–2154.

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How can Toujeo® help achieve glycaemic control?

BALANCE

between HbA_{1c} reduction & hypoglycaemia risk

In a broad type 1 diabetes population, Toujeo® demonstrated effective and comparable glycaemic control with lower risk of severe hypoglycaemia versus insulin glargine 100 units/mL[1]

STABLE PROFILE*

In adults with type 1 diabetes, Toujeo® has less glucose fluctuation than insulin glargine 100 U/mL[2] and less within-day variability of glucose lowering effect at a clinically relevant dose (0.4 units/kg/day) than insulin degludec 100 U/mL[3]

SUPPORT

available with Toujeo®

- **Toujeo** DoubleStar pen
- **Toujeo** education materials

ACQUISITION COST†

- Toujeo® has a lower acquisition cost to insulin degludec 100 units/mL

*The clinical implications of PK/PD data require further evaluation including CGM & larger clinical studies. Results of euglycaemic clamp studies do not necessarily predict clinical outcomes in all patients.
†Insulin glargine 100 U/mL and Toujeo® are not bioequivalent, a higher dose of Toujeo® (~10–18%) may be needed to achieve target ranges for plasma glucose levels, as shown in the treat-to-target randomised controlled trials.[4] In the treat-to-target BRIGHT trial, at Week 24 Toujeo® insulin dose was higher by 0.11 units/kg than degludec 100 U/mL dose.[5]

1. Danne T, et al. Diabetes Obes Metab. 2020;22:1880–5. **2.** Bergenstal RM, et al. Diabetes Care 2017;40:554-560. **3.** Bailey TS, et al. Diabetes Metab. 2018;44:15–21. **4.** Toujeo SmPC. **5.** Rosenstock J, et al. Diabetes Care. 2018;41:2147–2154.

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Prescribing Information: Toujeo® (insulin glargine 300 units/ml)

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Toujeo SoloStar pre-filled pens each ml contains 300 units of insulin glargine. SoloStar pen contains 1.5ml (450 units) of solution for injection. DoubleStar pen contains 3ml (900 units) of solution for injection.
Indication: Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years**.**
Dosage and Administration: Toujeo is administered subcutaneously, by injection into the abdominal wall, the deltoid or the thigh, once daily, at any time of the day, preferably at the same time every day. The dose regimen (dose and timing) should be adjusted according to individual response. Injection sites must be rotated within a given injection area from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Do not administer intravenously. In type 1 diabetes mellitus, Toujeo must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements. In patients with type 2 diabetes mellitus, recommended daily starting dose is 0.2 units/kg followed by individual dose adjustments. Toujeo can also be given together with other anti-hyperglycaemic medicinal products. *Switch between insulin glargine 100 units/ml and Toujeo:* Insulin glargine 100 units/ml and Toujeo are not bioequivalent and are not directly interchangeable. When switching from insulin glargine 100 units/ml to Toujeo, this can be done on a unit-to-unit basis, but a higher Toujeo dose (approximately 10-18%) may be needed to achieve target ranges for plasma glucose levels. When switching from Toujeo to insulin glargine 100 units/ml, the dose should be reduced (approximately by 20%). *Switching from other basal insulins to Toujeo:* A change of dose and/or timing of the basal insulin and concomitant anti-hyperglycaemic treatment may be required. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia. Toujeo must not be mixed or diluted with any other insulin or other medicinal products. Close metabolic monitoring is recommended during a switch and in the initial weeks thereafter. SoloStar 1-80 units per single injection in steps of 1 unit and DoubleStar 2-160 units in steps of 2 units. When changing from Toujeo SoloStar to Toujeo DoubleStar, if the patient's previous dose was an odd number then the dose must be increased or decreased by 1 unit. Toujeo DoubleStar prefilled pen is recommended for patients requiring at least 20 units per day. **Special Populations:** *Elderly, renal and hepatic impairment:* Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. *Paediatric:* When switching basal insulin to Toujeo, dose reduction of basal and bolus insulin needs to be considered on an individual basis, in order to minimise the risk of hypoglycaemia.
Contraindications: Hypersensitivity to insulin glargine or any excipients.
Precautions and Warnings: *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Toujeo is not the insulin of choice for treatment of diabetic ketoacidosis. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. *Hypoglycaemia:* In case of insufficient glucose control or a tendency to hyper/hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered. Particular caution should be exercised, and intensified blood glucose monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include patients in whom glycaemic control is markedly improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or who are elderly. The prolonged effect of subcutaneous insulin glargine may delay recovery from hypoglycaemia. *Intercurrent illness:* Requires intensified metabolic monitoring and often it is necessary to adjust the insulin dose. *Insulin antibodies:* administration may cause insulin antibodies to form. *Use with pioglitazone:* Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. *Medication errors:* Insulin labels must always be checked before each injection to avoid errors between Toujeo and other insulins. Patients must be instructed to never use a syringe to remove Toujeo from the SoloStar or DoubleStar pre- filled pen, A new sterile needle must be attached before each injection. Needles must not be re-used. ***Pregnancy and breast- feeding:*** There is no data from exposed pregnancies in controlled clinical trials. However, there is a large amount of data on use of insulin glargine 100 units/ml in pregnant women indicating no specific adverse effects on pregnancy and no specific malformative nor feto/neonatal toxicity. The use of Toujeo may be considered during pregnancy, if clinically needed. Careful monitoring of glucose control is essential. It is unknown if insulin glargine is excreted in breast milk.
Interactions: Substances that affect glucose metabolism may require adjustment of insulin glargine.
Adverse Reactions: *Very common:* Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. *Common:* Lipohypertrophy, injection site reactions, including redness, pain, itching, hives, swelling, or inflammation. *Not known:* Cutaneous amyloidosis. *Prescribers should consult the SmPC in relation to other adverse reactions.*
GB List Price: SoloStar 3 x 1.5ml pens: £32.14; DoubleStar 3 x 3ml pens: £64.27
Legal Category: POM M**arketing Authorisation Number**: SoloStar 3 Pen pack: PLGB 04425/0817; DoubleStar 3 Pen pack: PLGB 04425/0818. **Marketing Authorisation Holder:** Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK **Further information is available from:** Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com. **Date of preparation:** September 2022. **MAT-XU-2203098 (V1.0)**

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to UK- drugsafety@sanofi.com

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Prescribing Information: Toujeo® (insulin glargine 300 units/ml)

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Toujeo SoloStar pre-filled pens each ml contains 300 units of insulin glargine. SoloStar pen contains 1.5ml (450 units) of solution for injection. DoubleStar pen contains 3ml (900 units) of solution for injection.
Indication: Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years**.**
Dosage and Administration: Toujeo is administered subcutaneously, by injection into the abdominal wall, the deltoid or the thigh, once daily, at any time of the day, preferably at the same time every day. The dose regimen (dose and timing) should be adjusted according to individual response. Injection sites must be rotated within a given injection area from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Do not administer intravenously. In type 1 diabetes mellitus, Toujeo must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements. In patients with type 2 diabetes mellitus, recommended daily starting dose is 0.2 units/kg followed by individual dose adjustments. Toujeo can also be given together with other anti-hyperglycaemic medicinal products. *Switch between insulin glargine 100 units/ml and Toujeo:* Insulin glargine 100 units/ml and Toujeo are not bioequivalent and are not directly interchangeable. When switching from insulin glargine 100 units/ml to Toujeo, this can be done on a unit-to-unit basis, but a higher Toujeo dose (approximately 10-18%) may be needed to achieve target ranges for plasma glucose levels. When switching from Toujeo to insulin glargine 100 units/ml, the dose should be reduced (approximately by 20%). *Switching from other basal insulins to Toujeo:* A change of dose and/or timing of the basal insulin and concomitant anti-hyperglycaemic treatment may be required. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia. Toujeo must not be mixed or diluted with any other insulin or other medicinal products. Close metabolic monitoring is recommended during a switch and in the initial weeks thereafter. SoloStar 1-80 units per single injection in steps of 1 unit and DoubleStar 2-160 units in steps of 2 units. When changing from Toujeo SoloStar to Toujeo DoubleStar, if the patient's previous dose was an odd number then the dose must be increased or decreased by 1 unit. Toujeo DoubleStar prefilled pen is recommended for patients requiring at least 20 units per day. **Special Populations:** *Elderly, renal and hepatic impairment:* Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. *Paediatric:* When switching basal insulin to Toujeo, dose reduction of basal and bolus insulin needs to be considered on an individual basis, in order to minimise the risk of hypoglycaemia.
Contraindications: Hypersensitivity to insulin glargine or any excipients.
Precautions and Warnings: *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Toujeo is not the insulin of choice for treatment of diabetic ketoacidosis. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. *Hypoglycaemia:* In case of insufficient glucose control or a tendency to hyper/hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered. Particular caution should be exercised, and intensified blood glucose monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include patients in whom glycaemic control is markedly improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or who are elderly. The prolonged effect of subcutaneous insulin glargine may delay recovery from hypoglycaemia. *Intercurrent illness:* Requires intensified metabolic monitoring and often it is necessary to adjust the insulin dose. *Insulin antibodies:* administration may cause insulin antibodies to form. *Use with pioglitazone:* Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. *Medication errors:* Insulin labels must always be checked before each injection to avoid errors between Toujeo and other insulins. Patients must be instructed to never use a syringe to remove Toujeo from the SoloStar or DoubleStar pre- filled pen, A new sterile needle must be attached before each injection. Needles must not be re-used. ***Pregnancy and breast- feeding:*** There is no data from exposed pregnancies in controlled clinical trials. However, there is a large amount of data on use of insulin glargine 100 units/ml in pregnant women indicating no specific adverse effects on pregnancy and no specific malformative nor feto/neonatal toxicity. The use of Toujeo may be considered during pregnancy, if clinically needed. Careful monitoring of glucose control is essential. It is unknown if insulin glargine is excreted in breast milk. ***Interactions:*** Substances that affect glucose metabolism may require adjustment of insulin glargine.
Adverse Reactions: *Very common:* Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. *Common:* Lipohypertrophy, injection site reactions, including redness, pain, itching, hives, swelling, or inflammation. *Not known:* Cutaneous amyloidosis. *Prescribers should consult the SmPC in relation to other adverse reactions.*
NI List Price: SoloStar 5 x 1.5ml pens: £53.57; DoubleStar 3 x 3ml pens: £64.27.
Legal Category: POM **Marketing Authorisation Number**: SoloStar 5 Pen pack: EU/1/00/133/035; DoubleStar 3 Pen pack: EU/1/00/133/038. **Marketing Authorisation Holder:** Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. **Further information is available from:** Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com. **Date of preparation:** September 2022.**MAT-XI-2200061 (V1.0)**

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to UK- drugsafety@sanofi.com

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Prescribing Information: Lantus® (insulin glargine) 100 units/ml solution for injection

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentations: Lantus 100 units/ml solution for injection in a vial or in a cartridge. Lantus SoloStar 100 units/ml solution for injection in a pre-filled pen. Lantus cartridges and Solostar pre- filled pens each contain 3 ml of solution for injection, equivalent to 300 units insulin glargine. Each vial contains 10 ml of solution for injection, equivalent to 1000 units.

Indications: Treatment of diabetes mellitus in adults, adolescents and children of 2 years or above.

Dosage and administration: Lantus is administered subcutaneously once daily, at any time but at the same time each day. Injection sites must be rotated within a given injection area from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Do not administer intravenously. Lantus dosage should be individually adjusted. In type 2 diabetes mellitus, Lantus can also be used in combination with orally active antidiabetic medicinal products. Lantus must not be mixed with other insulins or diluted. Switch from twice daily NPH insulin to Lantus: To reduce the risk of nocturnal and early morning hypoglycaemia, patients who are changing their basal insulin regimen from a twice daily NPH insulin to a once daily regimen with Lantus should reduce their daily dose of basal insulin by 20 – 30% during the first weeks of treatment. Switch from Toujeo (insulin glargine) 300 units/ml to Lantus: Lantus and Toujeo are not bioequivalent and are not directly interchangeable. To reduce the risk of hypoglycemia, patients who are changing their basal insulin regimen from an insulin regimen with once daily Toujeo to a once daily regimen with Lantus should reduce their dose by approximately 20%. Switching from other insulins to Lantus: When switching from a treatment regimen with an intermediate or long-acting insulin to a regimen with Lantus, a change of the dose of the basal insulin may be required and the concomitant antidiabetic treatment may need to be adjusted (dose and timing of additional regular insulins or fast-acting insulin analogues or the dose of oral antidiabetic medicinal products). Close metabolic monitoring is recommended during, and for a period after, transition from other insulins to Lantus. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia.

Special populations: Elderly, renal or hepatic impairment: Insulin requirements may be diminished. Paediatric population (<2 years of age): No data are available.

Contraindications: Hypersensitivity to insulin glargine or any excipients.

Precautions and warnings: Lantus is not the insulin of choice for treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hypo/hyperglycaemic episodes all relevant factors must be reviewed before dose adjustment is considered. Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Injection technique: Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. Intercurrent illness also requires intensified metabolic monitoring. Hypoglycaemia: Particular caution should be exercised, and intensified blood monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups. The prolonged effect of subcutaneous Lantus may delay recovery from hypoglycaemia. Due to more sustained basal insulin supply with Lantus, less nocturnal but earlier morning hypoglycaemia can be expected. Insulin antibodies: administration may cause insulin antibodies to form. Rarely, this may necessitate dose adjustment. Pioglitazone: Cases of cardiac failure have been reported, especially in patients with risk factors for development of cardiac heart failure. Patients on this combination should be observed and pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Medication errors: Insulin labels must always be checked before each injection to avoid errors between Lantus and other insulins. Lantus Solostar is only suitable for subcutaneous injections from its pre-filled pen. Lantus cartridges are only suitable for subcutaneous injections from specific reusable pens (please refer to SmPC for further details). If administration by syringe is necessary, a vial should be used. ***Interactions:*** A number of substances affect glucose metabolism and may require dose adjustment of Lantus. ***Pregnancy and lactation:*** No clinical data on exposed pregnancies from controlled clinical trials are available. A large amount of post-marketing data indicates no specific adverse effects of Lantus in pregnancy. Use of Lantus in pregnancy can be considered if clinically needed. Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters. Immediately after delivery, insulin requirements decline rapidly (increased risk of hypoglycaemia). Careful monitoring of glucose control is essential. It is unknown if Lantus is excreted in breast milk.

Adverse reactions: Very common: Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Common: Lipohypertrophy, injection site reactions. Uncommon: Lipoatrophy. Rare: Allergic reactions, visual impairment, retinopathy and oedema. Very rare: Dysgeusia, myalgia. Frequency not known: Cutaneous amyloidosis. *Prescribers should consult the SmPC in relation to other adverse reactions.*

Legal category: POM.

GB list price and Marketing Authorisation Number(s): 1 x 10ml Lantus vial (PLGB 04425/0814): £25.69; 5 x 3ml Lantus cartridge (PLGB 04425/0815): £34.75; 5 x 3ml Lantus SoloStar (PLGB 04425/0816): £34.75.

Marketing Authorisation Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.

For more information please contact: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.

Date of preparation: October 2022. **MAT-XU-2204110 (V1.0)**

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to uk-drugsafety@sanofi.com

Prescribing Information: Lantus® (insulin glargine) 100 units/ml solution for injection

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentations: Lantus 100 units/ml solution for injection in a vial or in a cartridge. Lantus SoloStar 100 units/ml solution for injection in a pre-filled pen. Lantus cartridges and Solostar pre- filled pens each contain 3 ml of solution for injection, equivalent to 300 units insulin glargine. Each vial contains 10 ml of solution for injection, equivalent to 1000 units.

Indications: Treatment of diabetes mellitus in adults, adolescents and children of 2 years or above.

Dosage and administration: Lantus is administered subcutaneously once daily, at any time but at the same time each day. Injection sites must be rotated within a given injection area from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Do not administer intravenously. Lantus dosage should be individually adjusted. In type 2 diabetes mellitus, Lantus can also be used in combination with orally active antidiabetic medicinal products. Lantus must not be mixed with other insulins or diluted. Switch from twice daily NPH insulin to Lantus: To reduce the risk of nocturnal and early morning hypoglycaemia, patients who are changing their basal insulin regimen from a twice daily NPH insulin to a once daily regimen with Lantus should reduce their daily dose of basal insulin by 20 – 30% during the first weeks of treatment. Switch from Toujeo (insulin glargine) 300 units/ml to Lantus: Lantus and Toujeo are not bioequivalent and are not directly interchangeable. To reduce the risk of hypoglycemia, patients who are changing their basal insulin regimen from an insulin regimen with once daily Toujeo to a once daily regimen with Lantus should reduce their dose by approximately 20%. Switching from other insulins to Lantus: When switching from a treatment regimen with an intermediate or long-acting insulin to a regimen with Lantus, a change of the dose of the basal insulin may be required and the concomitant antidiabetic treatment may need to be adjusted (dose and timing of additional regular insulins or fast-acting insulin analogues or the dose of oral antidiabetic medicinal products). Close metabolic monitoring is recommended during, and for a period after, transition from other insulins to Lantus. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia.

Special populations: Elderly, renal or hepatic impairment: Insulin requirements may be diminished. Paediatric population (<2 years of age): No data are available.

Contraindications: Hypersensitivity to insulin glargine or any excipients.

Precautions and warnings: Lantus is not the insulin of choice for treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hypo/hyperglycaemic episodes all relevant factors must be reviewed before dose adjustment is considered. Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Injection technique: Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. Intercurrent illness also requires intensified metabolic monitoring. Hypoglycaemia: Particular caution should be exercised, and intensified blood monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups. The prolonged effect of subcutaneous Lantus may delay recovery from hypoglycaemia. Due to more sustained basal insulin supply with Lantus, less nocturnal but earlier morning hypoglycaemia can be expected. Insulin antibodies: administration may cause insulin antibodies to form. Rarely, this may necessitate dose adjustment. Pioglitazone: Cases of cardiac failure have been reported, especially in patients with risk factors for development of cardiac heart failure. Patients on this combination should be observed and pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Medication errors: Insulin labels must always be checked before each injection to avoid errors between Lantus and other insulins. Lantus Solostar is only suitable for subcutaneous injections from its pre-filled pen. Lantus cartridges are only suitable for subcutaneous injections from specific reusable pens (please refer to SmPC for further details). If administration by syringe is necessary, a vial should be used. ***Interactions:*** A number of substances affect glucose metabolism and may require dose adjustment of Lantus. ***Pregnancy and lactation:*** No clinical data on exposed pregnancies from controlled clinical trials are available. A large amount of post-marketing data indicates no specific adverse effects of Lantus in pregnancy. Use of Lantus in pregnancy can be considered if clinically needed. Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters. Immediately after delivery, insulin requirements decline rapidly (increased risk of hypoglycaemia). Careful monitoring of glucose control is essential. It is unknown if Lantus is excreted in breast milk.

Adverse reactions: Very common: Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Common: Lipohypertrophy, injection site reactions. Uncommon: Lipoatrophy. Rare: Allergic reactions, visual impairment, retinopathy and oedema. Very rare: Dysgeusia, myalgia. Frequency not known: Cutaneous amyloidosis. *Prescribers should consult the SmPC in relation to other adverse reactions.*

Legal category: POM.

NI list price and Marketing Authorisation Number(s): 1 x 10ml Lantus vial (EU/1/00/134/012): £25.69; 5 x 3ml Lantus cartridge (EU/1/00/134/006): £34.75; 5 x 3ml Lantus SoloStar (EU/1/00/134/033): £34.75. **Marketing Authorisation Holder**: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany.

For more information please contact: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.

Date of preparation: October 2022 **MAT-XI-2200071 (V1.0)**

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Sanofi Tel: 0800 090 2314.

Alternatively, send via email to uk-drugsafety@sanofi.com