Toujeo®
insulin glargine 300U/mL

Glycaemic control and hypoglycaemia during basal insulin initiation in type 2 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.

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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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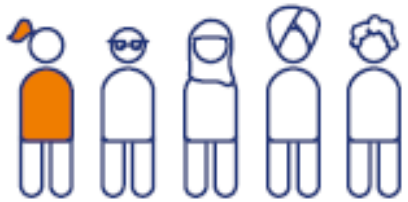
Diabetes UK - facts and stats

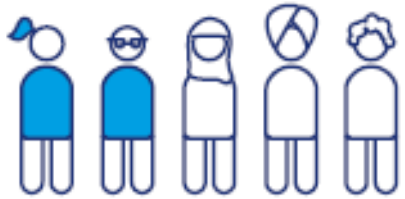
5.6 million

people in UK have **diabetes**[1]



Fewer than one in five

people with **Type 1** diabetes are meeting the recommended treatment targets that will reduce their risk of complications[2]



Two in five

people with **Type 2** diabetes are meeting the recommended treatment targets that will reduce their risk of complications[2]

1. https://www.diabetes.org.uk/about-us/about-the-charity/our-strategy/statistics - accessed November 2024
2. https://www.diabetes.org.uk/resources-s3/2019-11/facts-stats-update-oct-2019.pdf - Diabetes UK. Us, diabetes and a lot of facts and stats_ January 2019 - accessed November 2024

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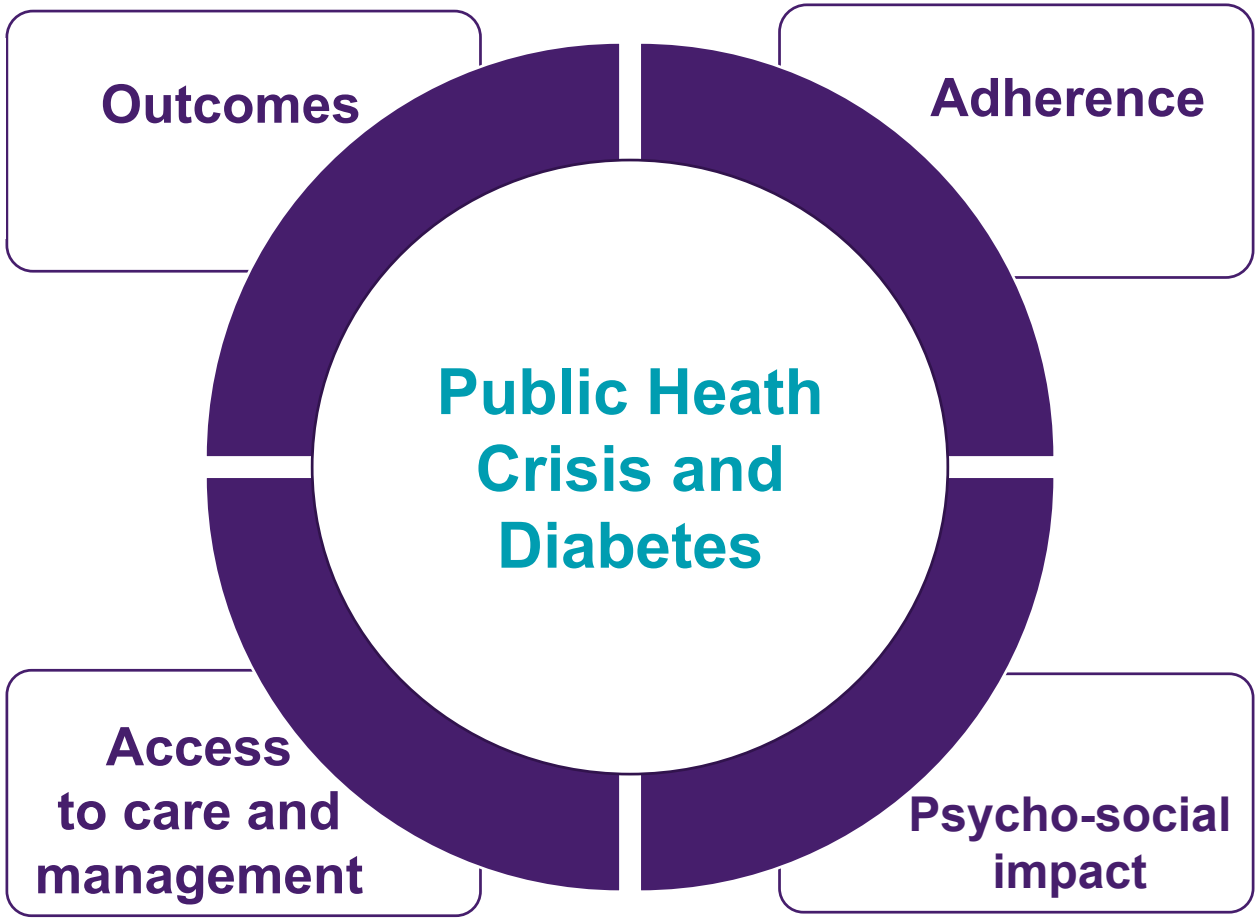
Public health crises pose both direct and indirect risks to people with diabetes

People with diabetes experience **worse outcomes** than the general population in times of a health crises[1]

Psychological impact of the pandemic may have left many patients with chronic diseases with little hope of improving their health outcomes, thereby **decreasing adherence**[4]



Reduced access to diabetes care and management in time of health crises adds to the challenge of blood glucose control and the mitigation of comorbidities[1,2]

Emotional and behavioral changes are increasing for people with diabetes in response to a crisis[3]

1. ADA Diabetes Care 201:30(9)2395
2. Kocurek B et al. Information for Health Care Professionals. Switching between insulin products in Disaster Response Situation, 2018
3. Dubey S et al. DMSCRR 2020; 14:779-88
4. Kretchy I A. et al. Research in Social and Administrative Pharmacy, https://doi.org/10.1016/j.sapharm.2020.04.007

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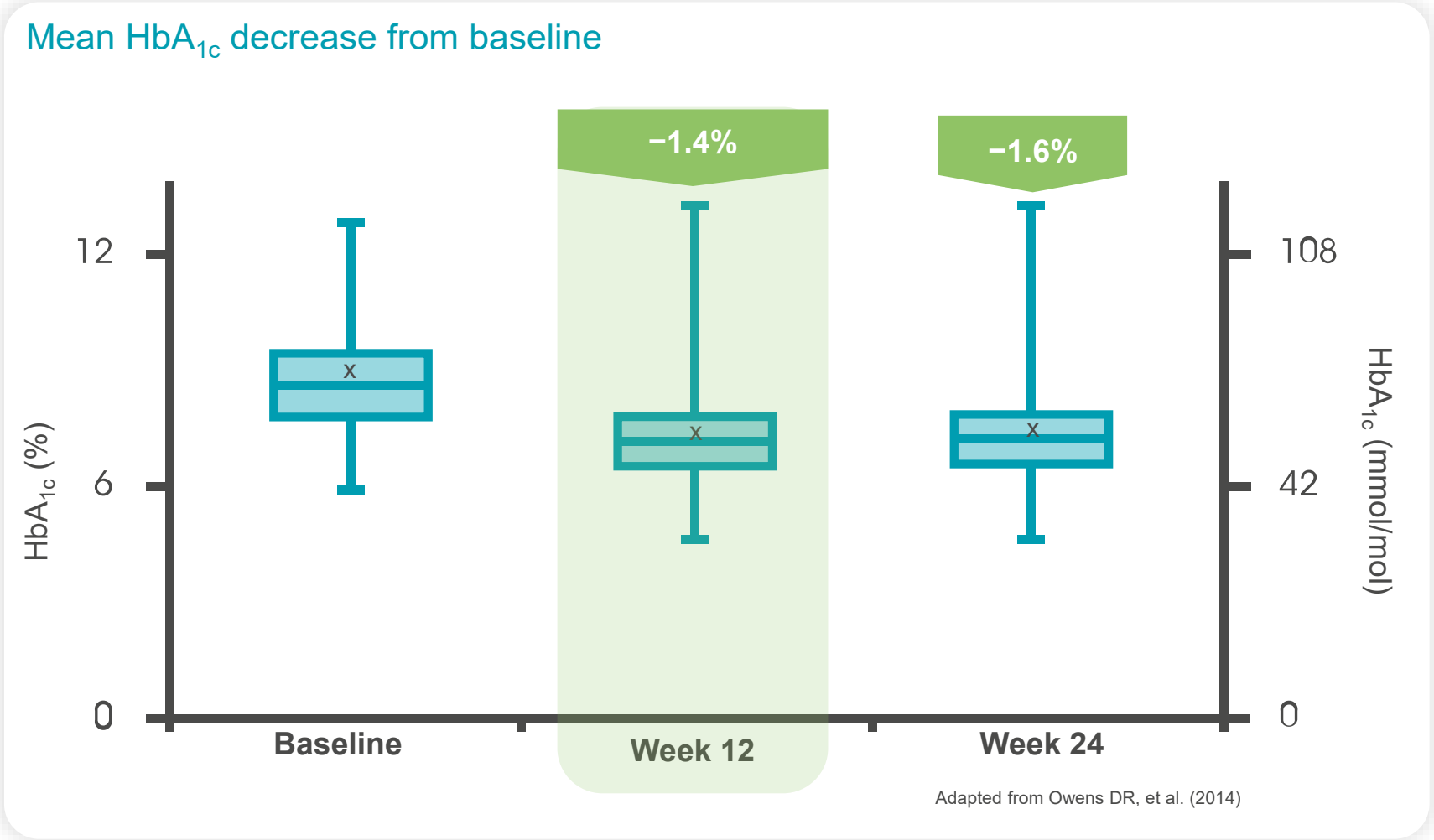
The majority of HbA_{1c} reduction with insulin is achieved in the first 12 weeks

Pooled data of treatment arms of 15 treat-to-target RCTs in T2DM (n=2837)



- Insulin glargine 100 U/mL was added to metformin, SU, or both
- Target FPG was 5.6 mmol/L

Box and whisker plot description: lower whisker represents the minimum value; bottom of lower box rests on the first quartile; midline of box represents median value; x represents mean value; top of upper box represents the third quartile; upper whisker represents the maximum value.

FPG, fasting plasma glucose; RCT, randomised controlled trial; T2DM, type 2 diabetes mellitus

Owens DR, et al. Diabetes Res Clin Pract. 2014;106:264–74.

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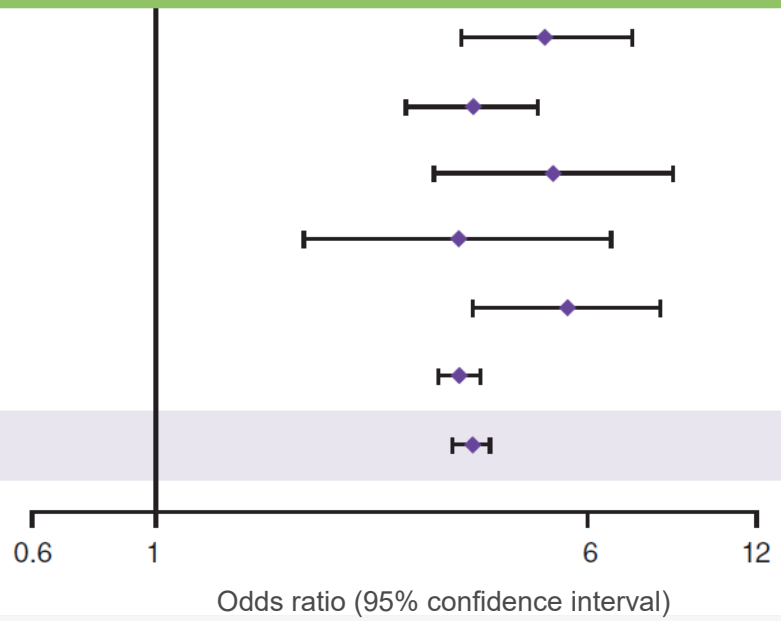
Early glycaemic response in first 12 weeks predicted long-term glycaemia

Real-world retrospective data of basal insulin initiation in type 2 diabetes (n=40,627)

Risk of not reaching target HbA_{1c} ≤53 mmol/mol (7.0%) after 24 months if patient does not achieve target in first 3 months

Country	Odds ratio	95% Confidence interval
France	5.04	3.53–7.18
Germany	3.71	2.84–4.85
Italy	5.22	3.19–8.52
Spain	3.50	1.85–6.62
UK	5.51	3.73–8.13
USA	3.51	3.21–3.84
Overall	**3.70**	**3.41–4.00**



Adapted from Mauricio D, et al. (2017)

3.7x

more likely to have HbA_{1c} >53 mmol/mol (7%) at 24 months[1]

(OR, 3.70, 95% CI: 3.41–4.00)

A multivariable logistic regression model assessed baseline and short-term (0-3 months post insulin initiation) factors associated with long-term (3-24 months) glycaemic control and hypoglycaemia. Overall OR was derived from a meta-analysis of results from all 6 countries, using an inverse-variance weighted method.

Mauricio D, et al. Diabetes Obes Metab. 2017;19:1155–64.

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The impact of hypoglycaemia early in basal insulin initiation

Future hypoglycaemia risk

Early hypoglycaemia within the first 3 months after basal insulin initiation in type 2 diabetes is associated with an increase in long-term hypoglycaemia risk[1]

Future treatment discontinuation

Early hypoglycaemia within the first 6 months after basal insulin initiation in type 2 diabetes is associated with an increased risk of treatment discontinuation[2]

The risk of hospitalisation

Hypoglycaemia within the first 6 months after basal insulin initiation in type 2 diabetes is associated with an increased risk of hospitalisation[2]

Impact on quality of life

Experience of hypoglycaemia on basal insulin in type 2 diabetes may impair quality of life[3]

1. Mauricio D, et al. Diabetes Obes Metab. 2017;19:1155–64. 2. Dalal M, et al. Curr Med Res Opin. 2017;33:209–14. 3. Meneghini L, et al. Diabetes Obes Metab. 2018;20:1156–1165.

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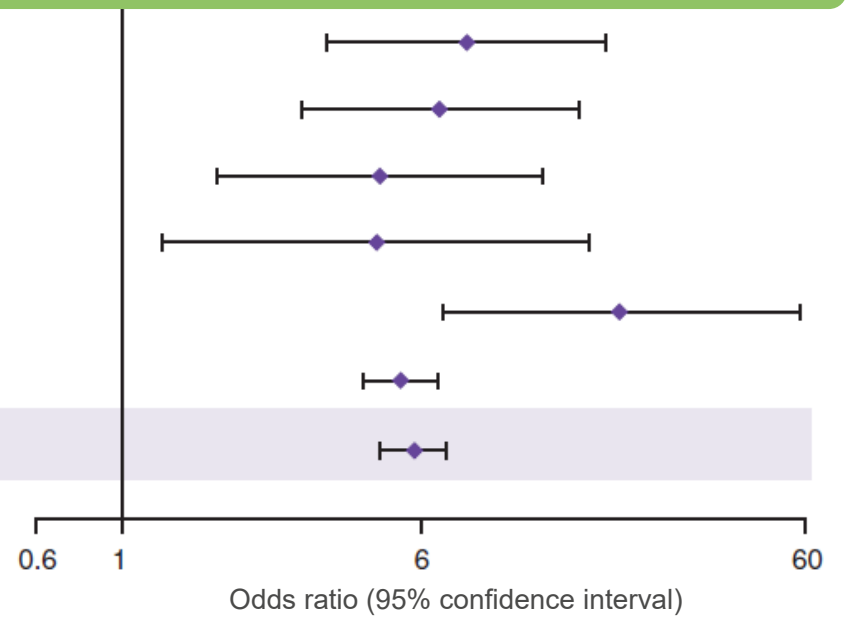
Early hypoglycaemia after basal insulin initiation increases the long-term risk

Real-world retrospective data of basal insulin initiation in type 2 diabetes (n=40,627)

Risk of hypoglycaemia (any reported hypoglycaemia or FPG ≤3.9 mmol/L) after 24 months if hypoglycaemia in first 3 months

Country	Odds ratio	95% Confidence interval
France	7.84	3.40–18.06
Germany	6.72	2.92–15.44
Italy	4.69	1.76–12.47
Spain	4.58	1.27–16.48
UK	19.97	6.85–58.19
USA	5.30	4.22–6.66
Overall	**5.71**	**4.67–6.99**



Adapted from Mauricio D, et al. (2017)

FPG, fasting plasma glucose

~5.7x

more likely to have hypoglycaemia at 24 months

(OR, 5.71, 95% CI: 4.67–6.99)

A multivariable logistic regression model assessed baseline and short-term (0-3 months post insulin initiation) factors associated with long-term (3-24 months) glycaemic control and hypoglycaemia. Overall OR was derived from a meta-analysis of results from all 6 countries, using an inverse-variance weighted method.

Mauricio D, et al. Diabetes Obes Metab. 2017;19:1155–64.

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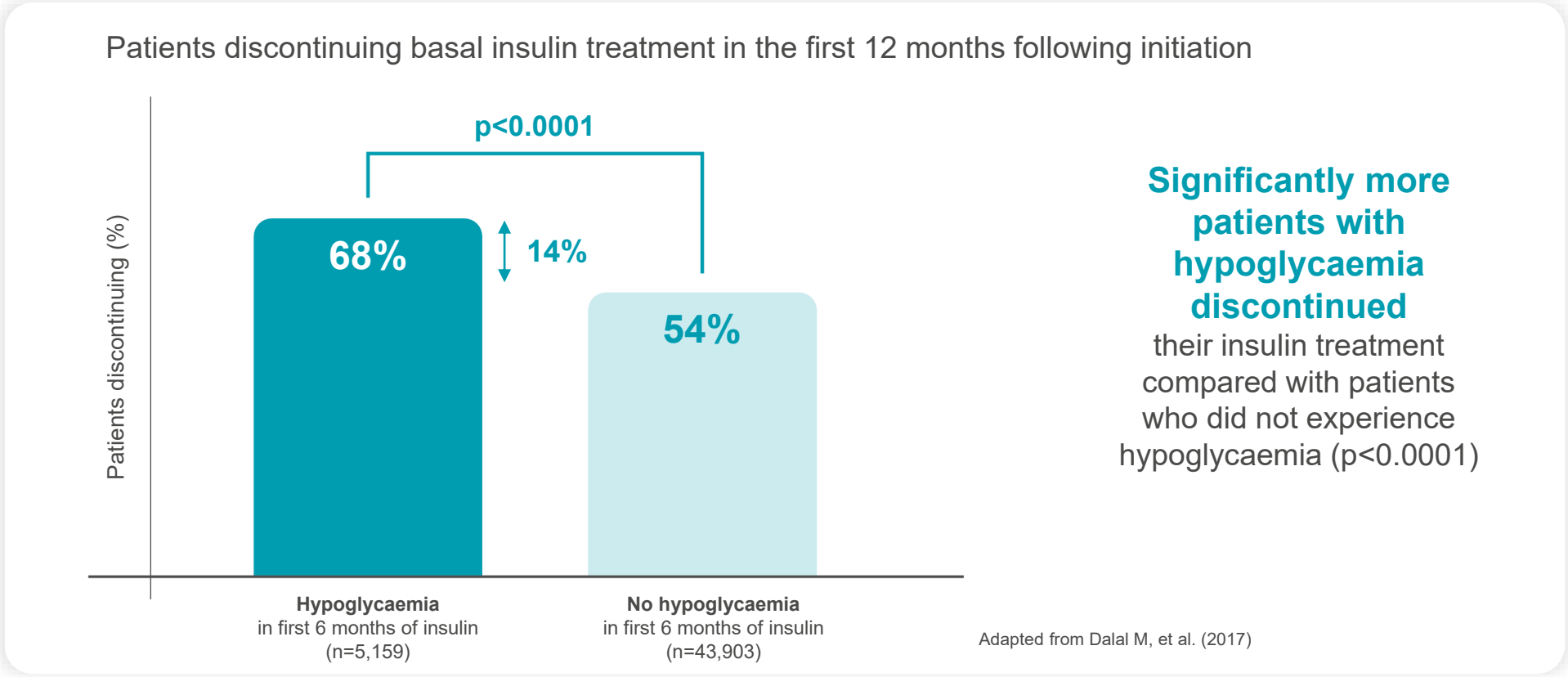
Hypoglycaemia within the first 6 months increases the risk of treatment discontinuation

Retrospective cohort study of insulin-naïve patients with type 2 diabetes (n=49,062)



Significantly more patients with hypoglycaemia discontinued their insulin treatment compared with patients who did not experience hypoglycaemia (p<0.0001)

Adapted from Dalal M, et al. (2017)

Study of patient-level data using electronic medical records of adult patients initiating basal insulin glargine, insulin detemir, or NPH. Patients were assigned to cohorts by experience of hypoglycaemia (ICD-9-CM code or laboratory glucose value ≤3.9 mmol/L) in the first 6 months following index date.

Dalal M, et al. Curr Med Res Opin. 2017;33:209–14.

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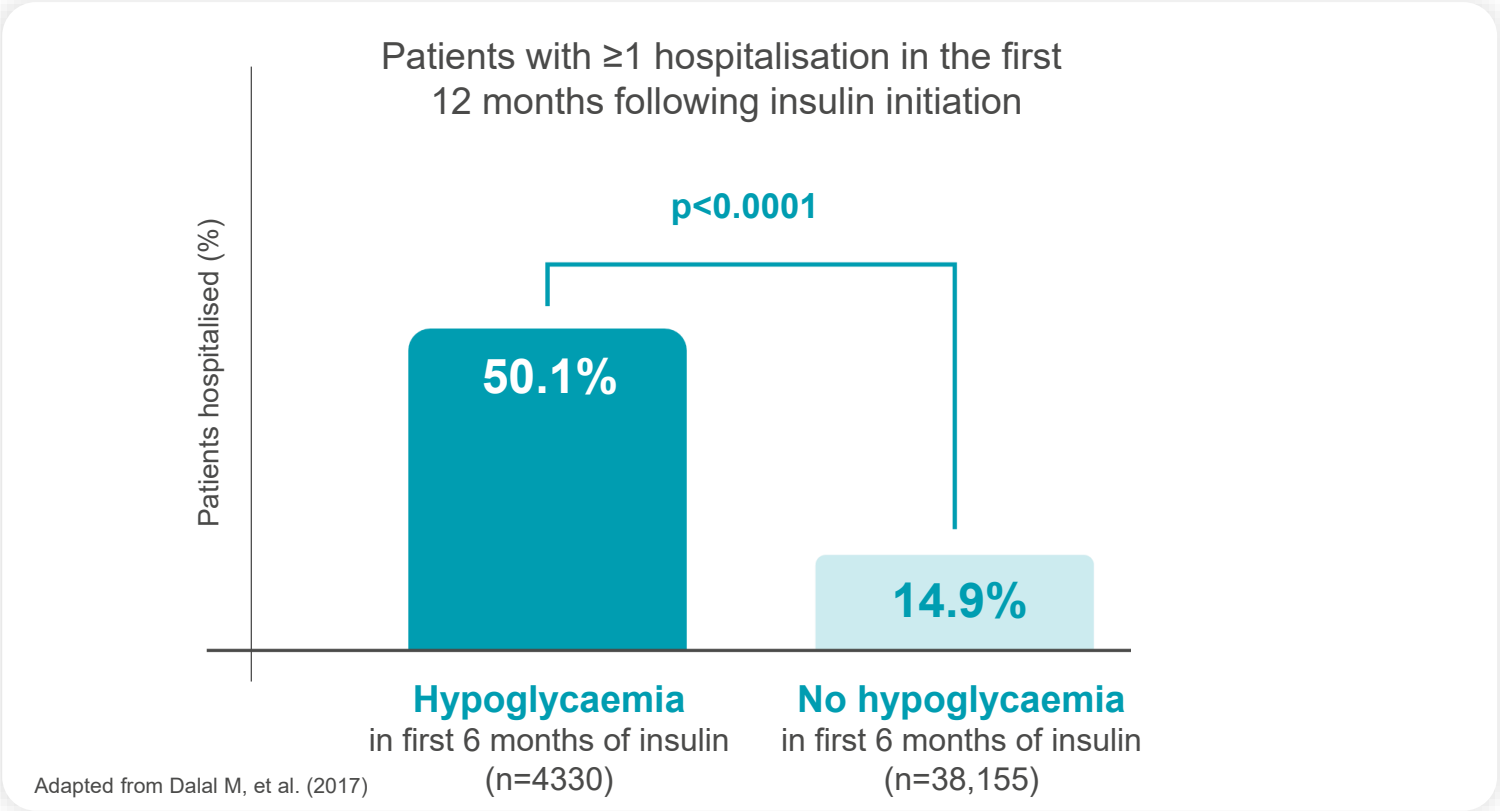
Hypoglycaemia within the first 6 months increases the risk of hospitalisation

Retrospective cohort study of insulin-naïve patients with type 2 diabetes



Adapted from Dalal M, et al. (2017)

4.7x
more likely to be hospitalised*

OR 4.7, 95% CI 4.4 to 5.1*

*After adjustment for confounders (demographics [age, race, gender, region, insurance], baseline clinical measures [hypoglycaemia, HbA_{1c},, body mass index] comorbidities, Charlson Comorbidity Index score, number of oral diabetes drugs], and baseline healthcare utilisation

Study of patient-level data using electronic medical records of adult patients initiating basal insulin glargine, insulin detemir, or NPH. Patients were assigned to cohorts by experience of hypoglycaemia (ICD-9-CM code or laboratory glucose value ≤3.9 mmol/L) in the first 6 months following index date.

OR, odds ratio; CI, confidence interval

Dalal M, et al. Curr Med Res Opin. 2017;33:209–14.

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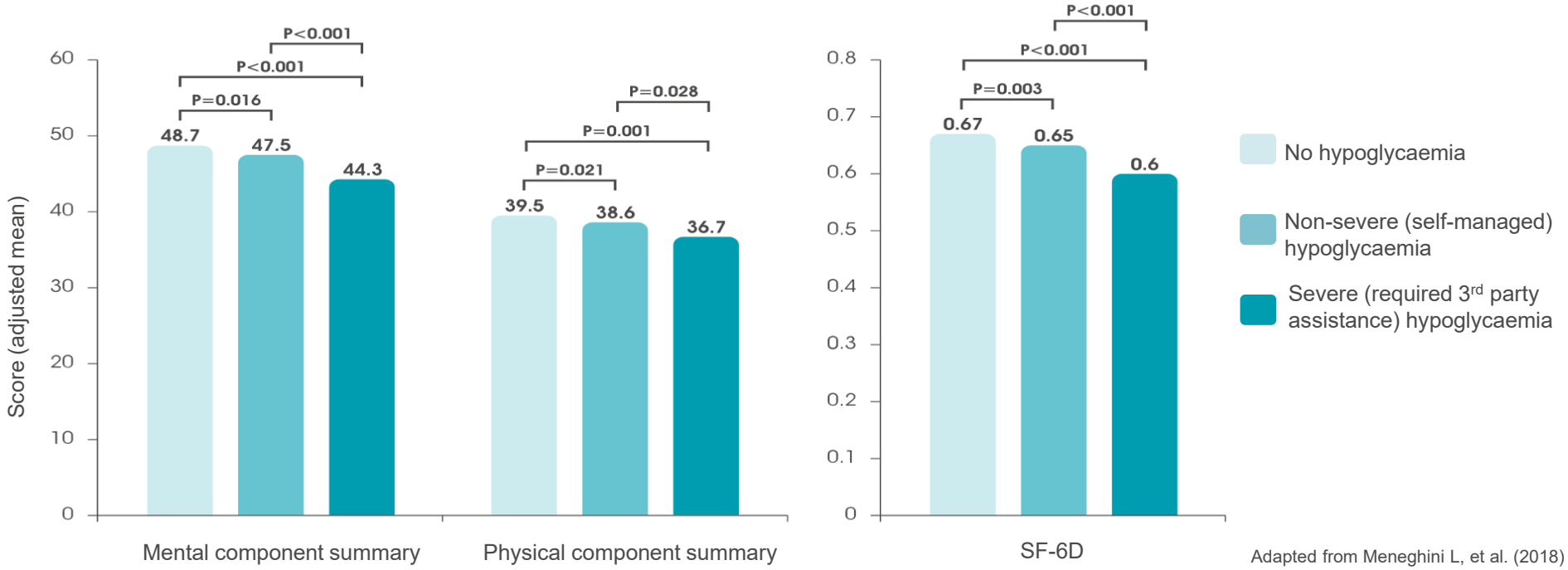
Hypoglycaemia in the previous year reduces a person's quality of life

Observational survey study of basal insulin-using patients with type 2 diabetes (n=2,423)

Health-related quality of life (HRQoL) in patients using basal insulin ± oral anti-diabetic drugs or rapid-acting/premixed insulin



Adapted from Meneghini L, et al. (2018)

HRQoL was assessed using the Medical Outcomes 12-item Short-Form Survey Instrument version 2 (SF-12v2) for the year 2011 and the 36-item Short-Form Survey Instrument version 2 (SF-36v2) for 2012 and 2013. SF-36v2 reports on health status in 8 domains, from which 2 summary scores are calculated: the Physical Component Summary and the Mental Component Summary, which are normed to a mean of 50 for the general US population; a higher score indicates better health status. SF-36v2 was used to generate health state utilities by applying the SF-6D algorithm, which takes items from the domains of the SF-36v2, and yields summary scores on a theoretical scale of 0 to 1. Higher scores indicate better health status.

Meneghini L, et al. Diabetes Obes Metab. 2018;20:1156–65.

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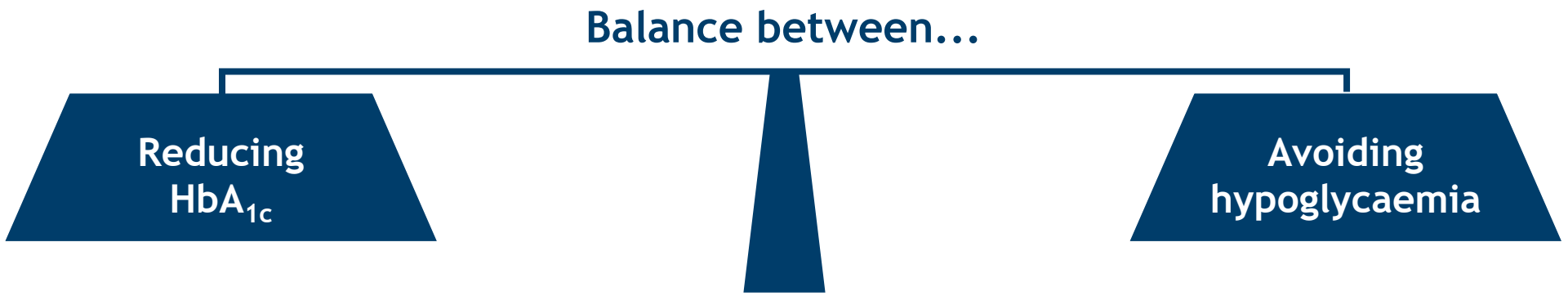
Balancing between HbA_{1c} reduction and avoidance of hypoglycaemia is key to reducing the risk of diabetes-related complications and improving adherence



1% decrease in HbA_{1c}

is associated with a **reduction in complications** by[1]….

- ⬇ 43% Amputation or fatal peripheral blood vessel disease*
- ⬇ 37% Microvascular complications e.g. CKD and blindness*
- ⬇ 21% Deaths related to diabetes*
- ⬇ 14% **Heart attack***
- ⬇ 12% **Stroke****

* p<0.0001; ** p=0.035

Early hypoglycaemia

after basal insulin initiation in type 2 diabetes is associated with an **increase in long-term hypoglycaemia** risk and treatment **discontinuation**[2,3]

- ~5.7x More likely to have hypoglycaemia at 24 months (odds ratio 5.71, 95% CI: 4.67–6.99)[2]
- +14% More patients with hypoglycaemia discontinued their insulin treatment compared with patients who did not experience hypoglycaemia (p<0.0001)

1. Stratton IM, et al. BMJ 2000; 321: 405–12. 2. Mauricio D, et al. Diabetes Obes Metab. 2017;19:1155–64. 3. Dalal M, et al. Curr Med Res Opin. 2017;33:209–14.

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How does Toujeo® differ from insulin glargine 100 U/mL and insulin degludec?

Toujeo®
insulin glargine 300U/mL

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What's the difference between Toujeo® and insulin glargine 100U/mL?

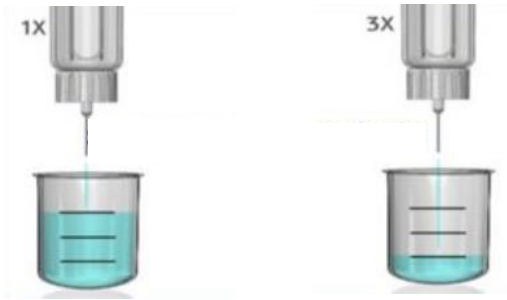
Smaller volume of injection for Toujeo® vs insulin glargine 100 U/mL

Smaller subcutaneous depot for Toujeo® vs insulin glargine 100U/mL

Different absorption kinetics which lead to a "more gradual release" of insulin

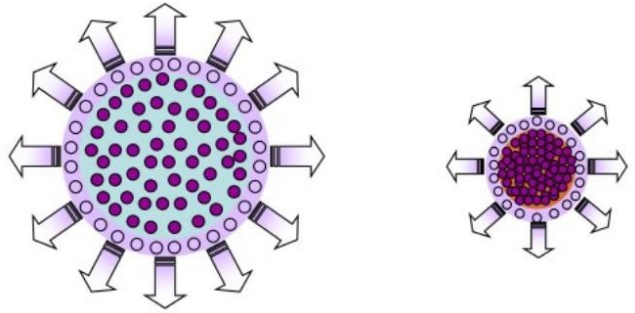
Distinct PK/PD profile for Toujeo® vs insulin glargine 100U/mL

Reduction of volume by 2/3



Insulin glargine 100U/mL Toujeo®

Smaller surface area



Insulin glargine 100U/mL Toujeo®

Toujeo® has the same mode of protraction (forming precipitates) and metabolism (main circulating moiety is M1) as insulin glargine 100U/mL

Dalley G, Lavernia F. Diabetes Obes Metab. 2015 Jul 3. doi: 10.1111/dom.12531.;
Steinstrasser A et al. Diabetes Obes Metab, 2014;16:873-6; Becker RH et al. Diabetes Care. 2015;38:637-43

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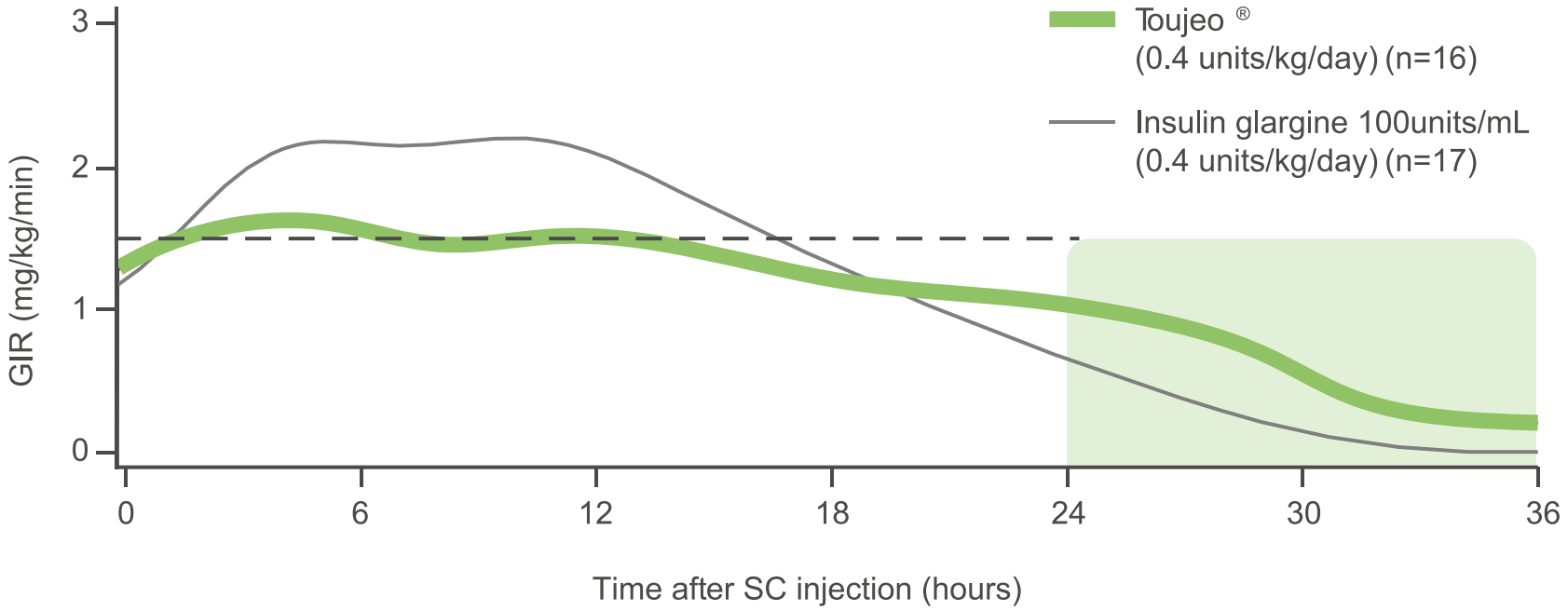
Toujeo® is associated with a more stable & prolonged activity profile than insulin glargine 100 U/mL

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.

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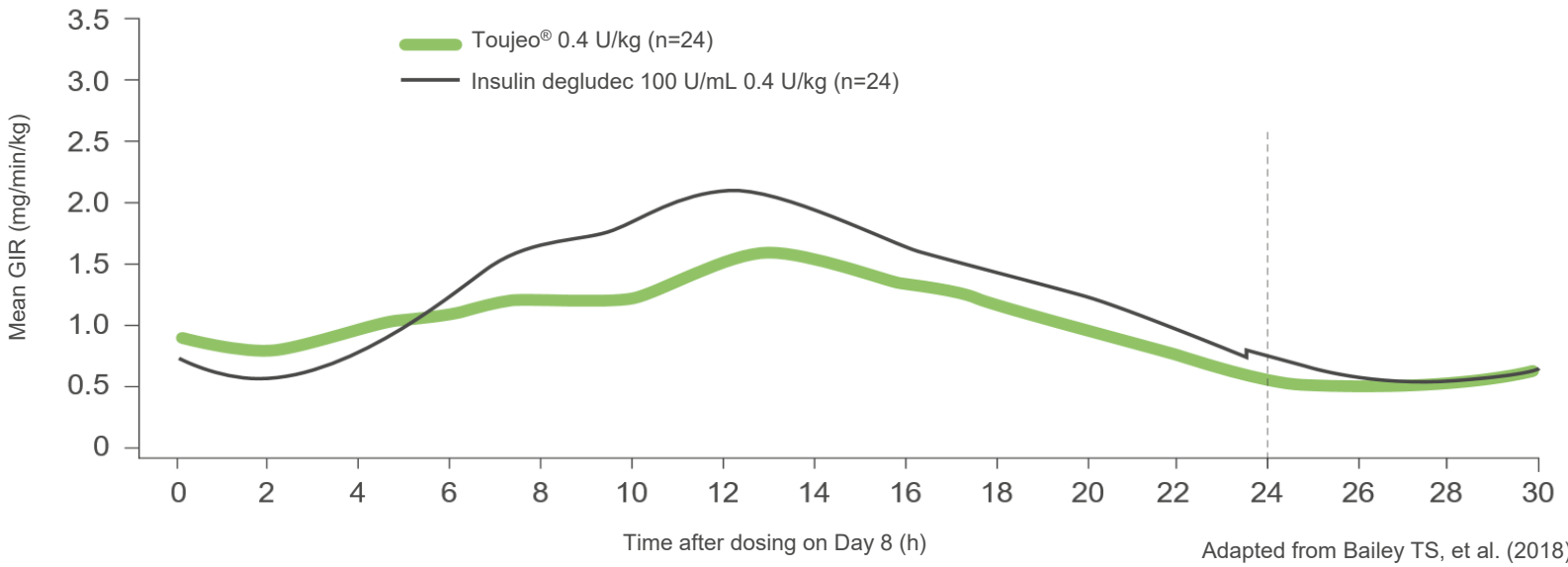
Less within-day fluctuation with Toujeo® vs insulin degludec 100 U/mL

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

1. Bailey TS, et al. Diabetes Metab. 2018;44:15–21.

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Toujeo®
insulin glargine 300U/mL

Can Toujeo® help to find the right balance between effective HbA_{1c} reductions and the risk of hypoglycaemia?

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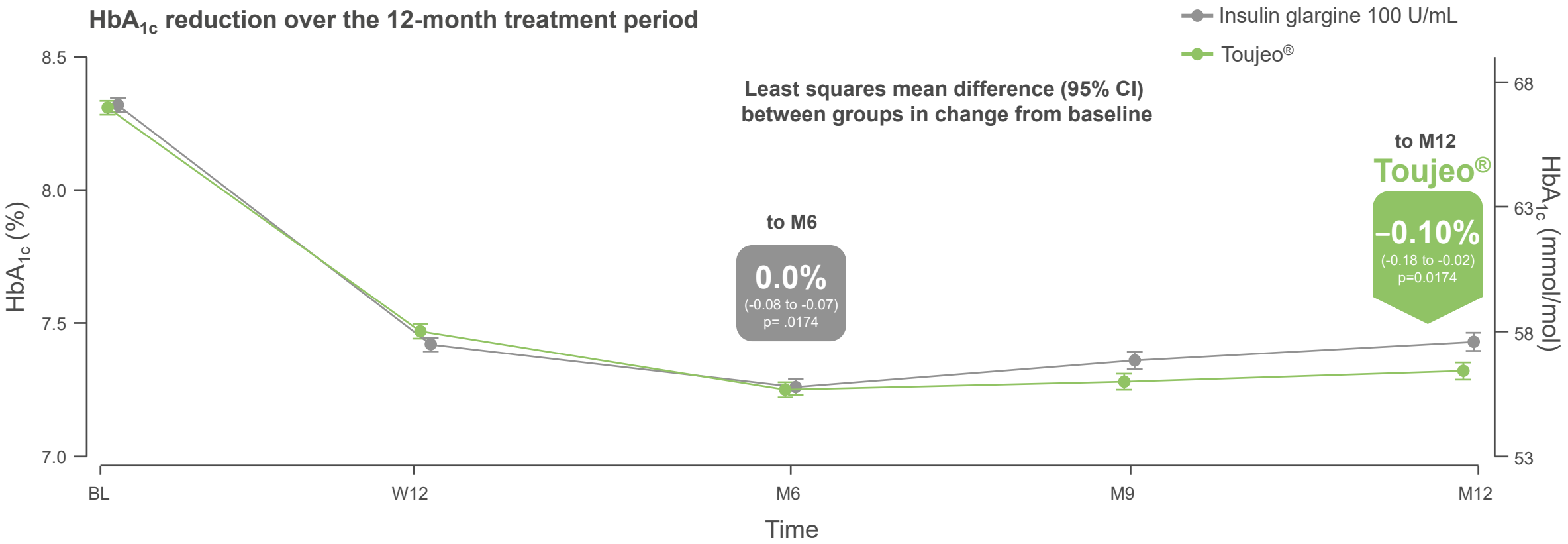
Better glycaemic control with Toujeo® (insulin glargine 300 U/mL) vs insulin glargine 100 U/mL at 12 months

Patient-level meta-analysis

Patient-level meta-analysis of EDITION 1, 2 and 3 in a large population with type 2 diabetes



mITT population: Toujeo®, n=1239; insulin glargine 100 U/mL, n=1235

Adapted from Ritzel R, et al. (2018)

M, month

Ritzel R. et al. Diabetes Obes Metab. 2018;20:541–548.

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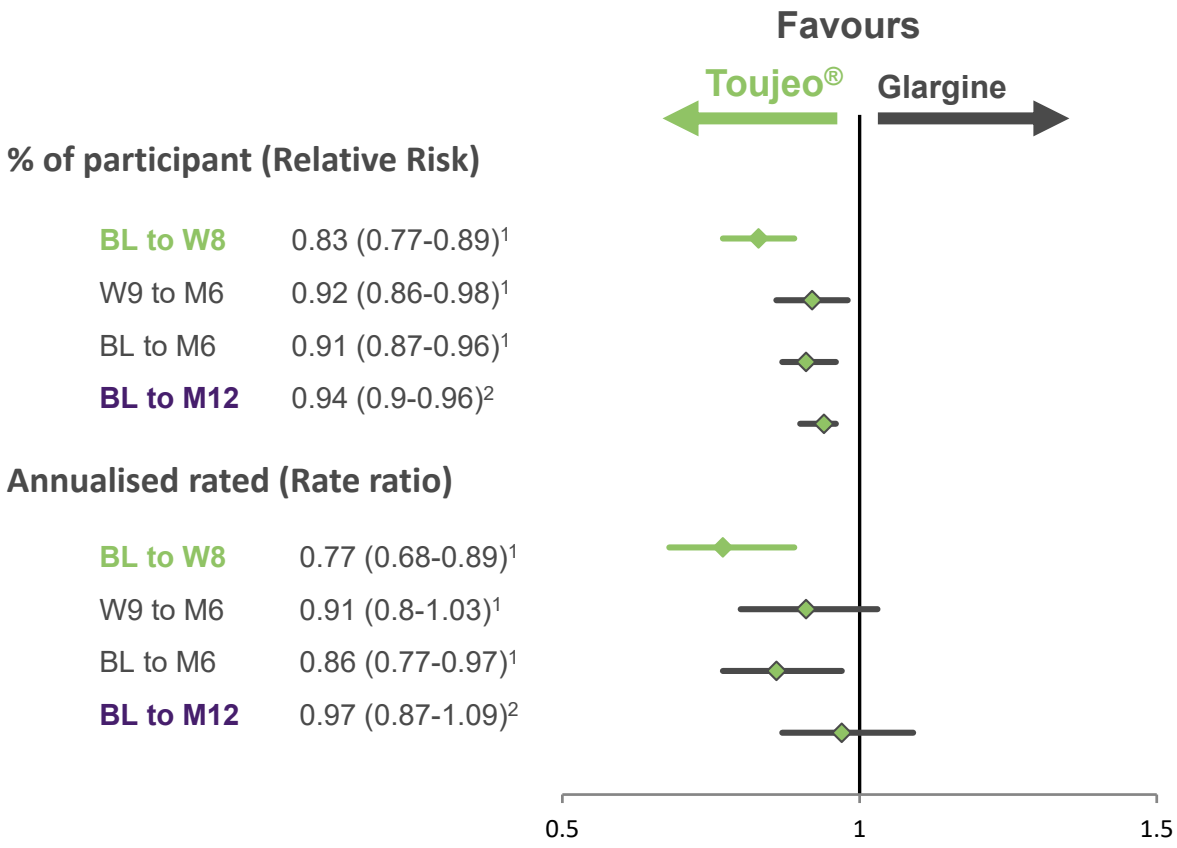
Less confirmed (≤3.9 mmol/l) or severe hypoglycaemia with Toujeo® vs insulin glargine 100 U/mL

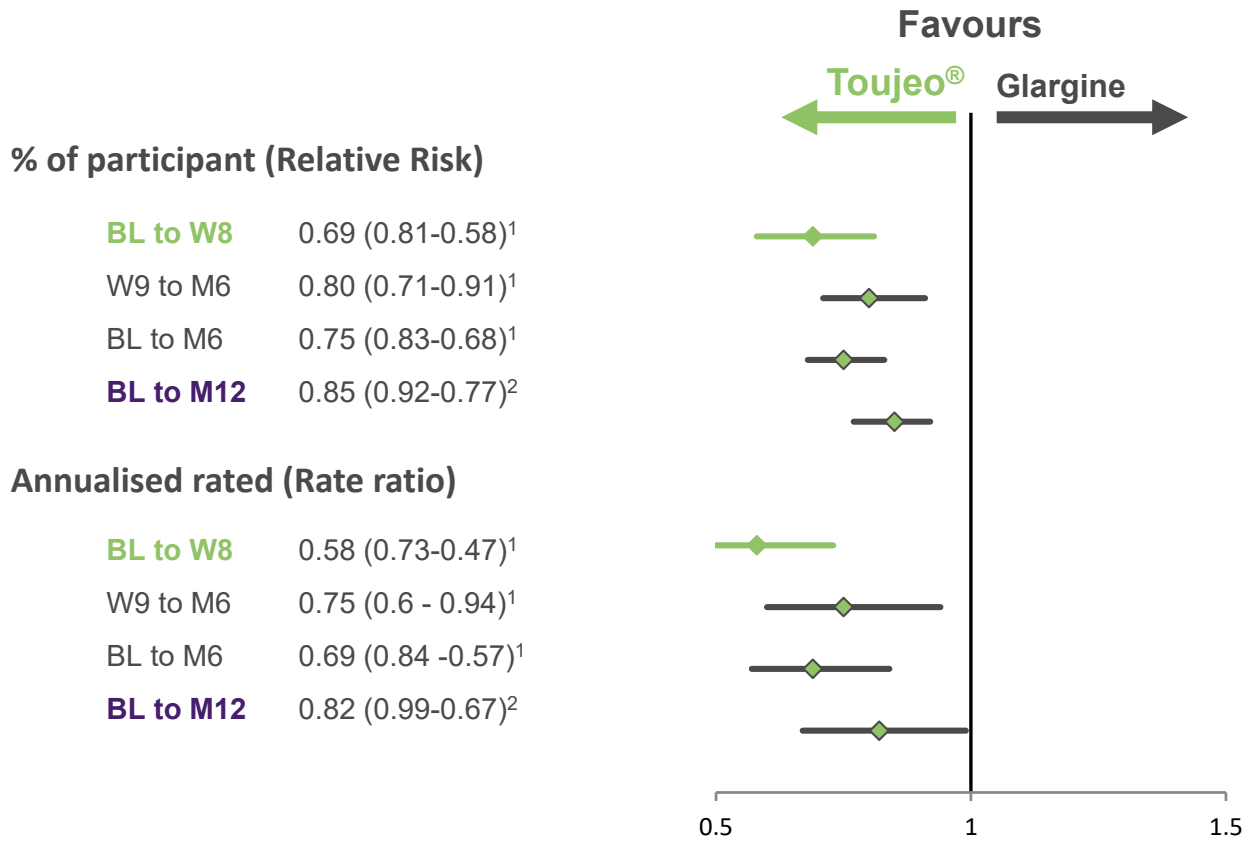
Patient-level meta-analysis

Patient-level meta-analysis of EDITION 1, 2 and 3 in a large population with type 2 diabetes

ANYTIME (confirmed (≤3.9 mmol/l) or severe hypoglycaemia)



NOCTURNAL (confirmed (≤3.9 mmol/l) or severe hypoglycaemia)



Modified from Ritzel R. et al, (2015) and (2018)
Safety population. Toujeo®, n=1242; Glargine 100U/mL, n=1246

1. Ritzel R. et al. Diabetes Obes Metab.2015;17:859–867. 2. Ritzel R. et al. Diabetes Obes Metab. 2018;20:541–548

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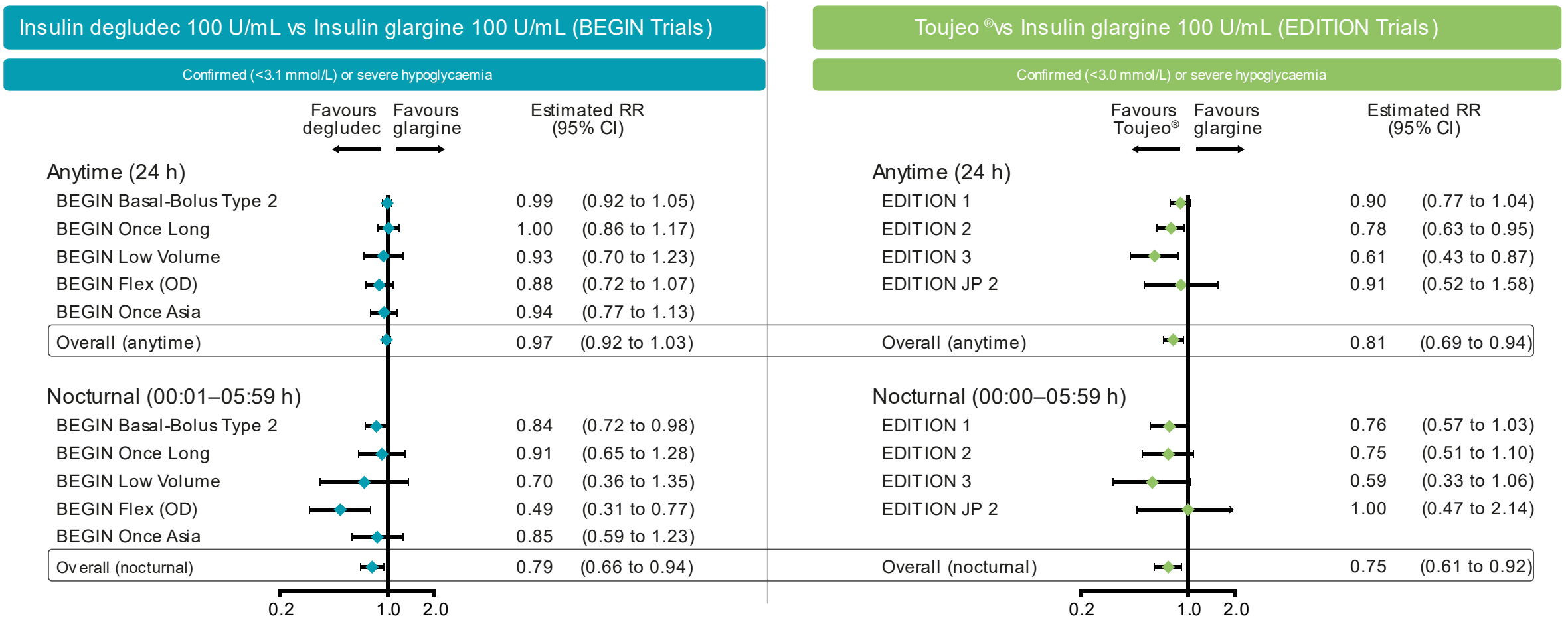
Hypoglycaemia in RCTs comparing 1st and 2nd-generation basal insulin analogues

Trial-level meta-analysis

Anytime (24 h) or nocturnal confirmed or severe hypoglycaemia with Toujeo® & insulin degludec vs insulin glargine 100 U/mL



Modified from Cheng A. et al, (2020)

CI, confidence interval; OD, once daily; RR, rate ratio; RCT, randomised controlled trial

Cheng A, et al Diabetes Metab Res Rev. 2020;e3329.

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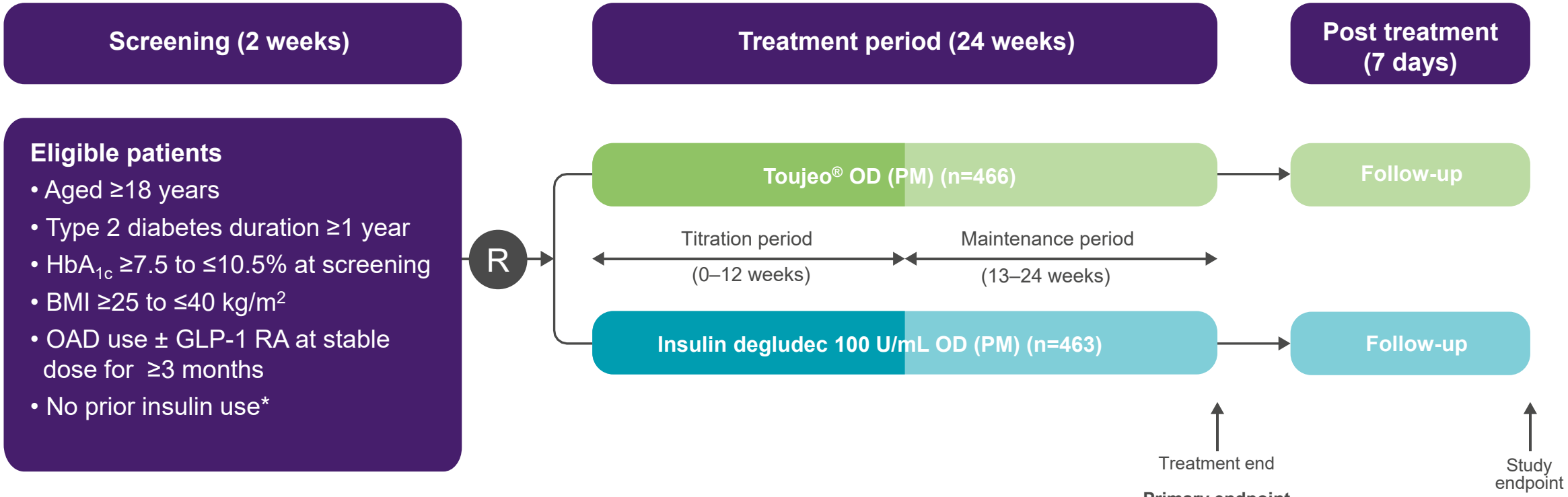
The first head-to-head trial of Toujeo® (insulin glargine 300 U/mL) vs insulin degludec 100 U/mL in people with T2DM

BRIGHT

RCT

Insulin-naïve adults with type 2 diabetes



Stratification by:

- HbA_{1c} at screening (<8.0/≥8.0% [<64/≥64 mmol/mol])
- Use of sulphonylurea or meglitinides at screening (Yes/No)

Primary endpoint
LSM change in HbA1c from baseline to week 24
Non-inferiority study (margin 0.3%)

Secondary endpoints
Incidence and event rates of confirmed hypoglycaemia during the 24-week on-treatment period, the active titration period (Weeks 0–12), and the maintenance period (Weeks 13–24)

Adverse events

*With the exception of a maximum of 8 consecutive days or 15 days total prior insulin use.
BMI, body mass index; degludec 100 U/mL, insulin degludec 100 U/mL; GLP-1 RA, glucagon-like peptide-1 receptor agonist; OAD, oral anti-hyperglycaemic drug; OD, once daily R, randomisation; RCT, randomised controlled trial

Rosenstock J, et al. Diabetes Care. 2018;41:2147–54.

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Titration of Toujeo® in the BRIGHT study

An illustration of a titration algorithm based on the BRIGHT clinical study

Median fasting self-monitored plasma glucose from last 3 days in range of:	Dose change*
>7.8 mmol/L	**+ 6 U**
>6.7 - ≤7.8 mmol/L	**+ 4 U**
>5.6 - ≤6.7 mmol/L	**+ 2 U**
≥4.4 - ≤5.6 mmol/L	**No change**
<4.4mmol/L or occurrence of 1 symptomatic confirmed hypoglycaemia episode documented in the preceding week	**- 2 U**

*Dose adjustment should not be more often than every 3 days

Before prescribing Toujeo®, always refer to the Summary of Product Characteristics.

This is a example on how to titrate Toujeo® based on the BRIGHT study and is for illustrative purposes. In clinical practice, titration should be adapted by the treating HCP based on the needs of individual patient characteristics. Patients on multiple anti-diabetic treatments are at an increased risk of hypoglycaemia and will require careful individual dose titration.

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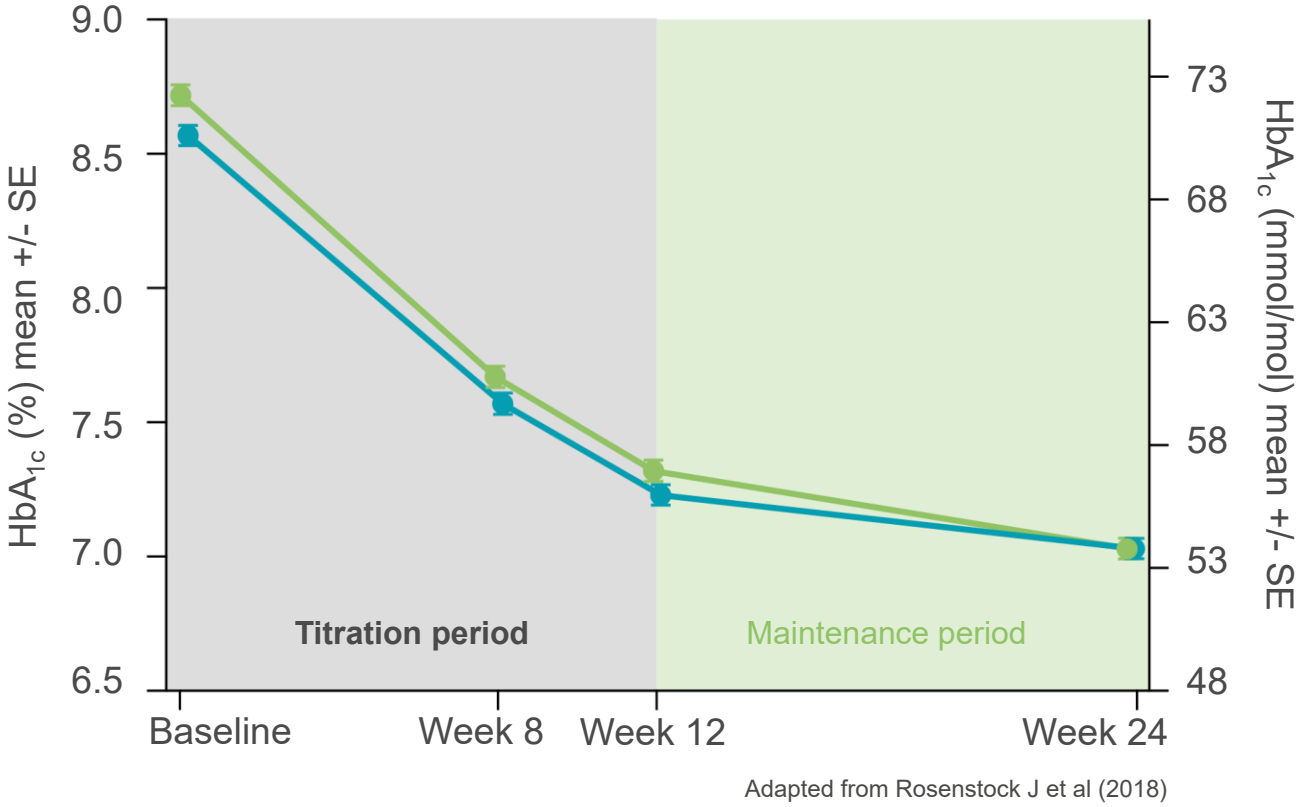
Comparable and effective HbA_{1c} reduction at 24 weeks with Toujeo® and insulin degludec 100 units/mL[1,2]

BRIGHT

HbA_{1c} levels over 24 weeks of treatment



Adapted from Rosenstock J et al (2018)

Primary endpoint

LSM change in HbA_{1c} from baseline to week 24*

Toujeo	Insulin degludec
8.72% ± 0.83%	8.57% ± 0.80%
−1.64%	−1.59%
(n=462)	(n=462)
7.03% ± 0.79%	7.03% ± 0.77%

Toujeo® non-inferior (margin 0.3%) vs degludec,

p<0.0001

Primary endpoint met

LSM change in HbA_{1c} from baseline to week 12*

Toujeo	Insulin degludec
−1.37%	−1.39%
(n=448)	(n=445)

LSM difference: −0.02% (95% CI: −0.08 to 0.12)

*HbA_{1c} LSM, least squares mean change; SE, standard error; insulin degludec, insulin degludec 100 units/mL

1. Rosenstock J, et al. Diabetes Care. 2018;41:2147–54. 2. Cheng A, et al. Diabetes Obes Metab. 2020;22:346–54.

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Comparable anytime overall hypoglycaemia, with lower event rate during the titration phase

BRIGHT

Rate of anytime (24 h) severe and/or documented hypoglycaemia (<3.0 mmol/L)

COMPARABLE

Full study period

Day 1- Week 24

Toujeo vs Degludec

0.61 vs 0.88

Events/patient-year

No difference

RR (95% CI): 0.69 (0.45 to 1.08), *p*=0.104

LOWER

Titration phase

Day 1–Week 12

Toujeo vs Degludec

0.49 vs 0.86

Events/patient-year

Toujeo -43%

RR 0.57 (95% CI, 0.34 to 0.97), p=0.038

ARR -0.4%

COMPARABLE

Maintenance phase

Week 13–Week 24

Toujeo vs Degludec

0.73 vs 0.91

Events/patient-year

No difference

RR 0.81 (95% CI, 0.48 to 1.39), p=0.448

***All p-values are analysed as nominal**

Safety population (Toujeo®, n=462; insulin degludec 100 units/mL, n=462)

ARR, absolute relative risk; CI, confidence interval; HbA1c, glycated haemoglobin; RR, rate ratio.

No specific safety concerns were reported. Overall, 202 (43.7%) and 221 (47.8%) of participants in the Toujeo and degludec treatment groups, respectively, reported adverse events during the 24-week study period.

Cheng A, et al. Diabetes Obes Metab. 2020;22:346–54.

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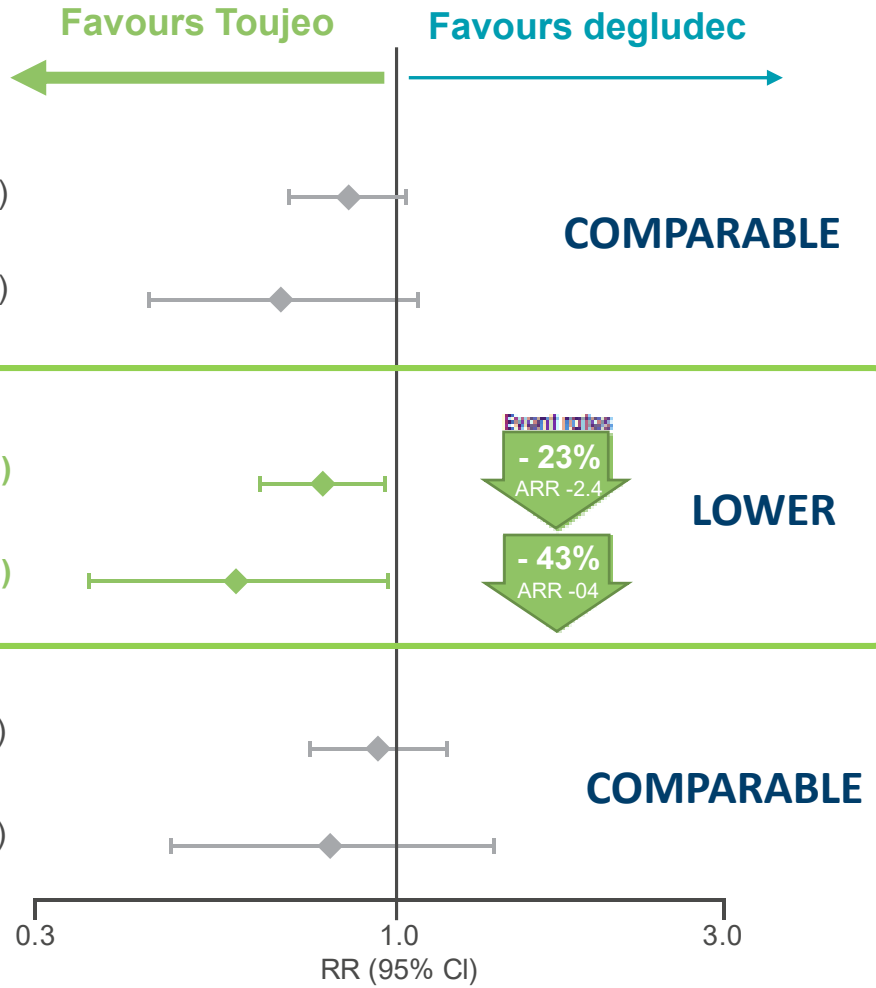
Comparable anytime overall hypoglycaemia, with lower event rate during the titration phase

		Events/patient year Toujeo	Degludec	
Full study period				
24-week period	Confirmed (≤3.9 mmol/L)	9.34	10.83	RR 0.86 (95% CI, 0.71 to 1.04)
	Confirmed (<3.0 mmol/L)	0.61	0.88	RR 0.69 (95% CI, 0.45 to 1.08)
Titration period				
0–12 weeks	**Confirmed (≤3.9 mmol/L)**	8.08	10.47	**RR 0.77 (95% CI, 0.62 to 0.96)**
	Confirmed (<3.0 mmol/L)	0.49	0.86	**RR 0.57 (95% CI, 0.34 to 0.97)**
Maintenance period				
13–24 weeks	Confirmed (≤3.9 mmol/L)	10.64	11.21	RR 0.95 (95% CI, 0.76 to 1.19)
	Confirmed (<3.0 mmol/L)	0.73	0.91	RR 0.81 (95% CI, 0.48 to 1.39)



Adapted from Rosenstock J, et al. (2018)

RR, relative risk; CI, confidence interval, degludec, insulin degludec 100 units/mL

Rosenstock J, et al. Diabetes Care. 2018;41:2147–54.

How to start Toujeo® and support your insulin-naïve patients

Toujeo®
insulin glargine 300U/mL

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How to start Toujeo® in your insulin-naïve patients

Dosing details for initiation and titration in type 2 diabetes

- Determine your patient's starting dose based on body weight
- The recommended starting dose is 0.2 U/kg

- Units of Toujeo® are rounded down to the nearest whole unit
- For example, 89 kg x 0.2 U/kg = 17 units

- Set titration goals based on your patient’s needs
- These should be individualised and based on a fasting glucose goal

- Adjust and titrate the dose of Toujeo® as required
- Monitor glucose frequently in the first few weeks of therapy

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

Toujeo Summary of Product Characteristics

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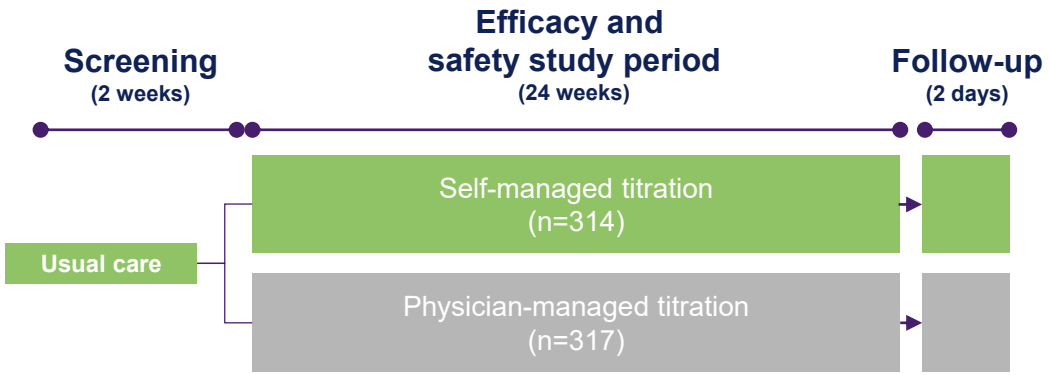
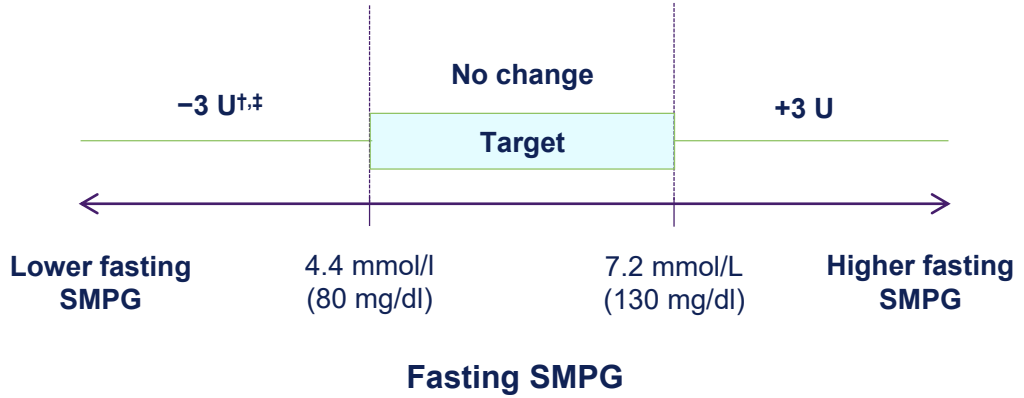
TAKE CONTROL study in insulin-naïve or pre-treated people with T2DM

Study design



EudraCT Number: 2015-001626-42

Titration algorithm of Toujeo® (both groups)



In the physician-managed titration algorithm, doses were titrated at each visit according to study design (weekly for the first eight weeks, biweekly until week 12, and then monthly until week 24). In the self-managed titration algorithm, the dose was titrated every 3–4 days.

Patients in the self-managed group were instructed on the use of the algorithm but made decisions regarding titration on their own

†Dose adjustment is −3 U or at the discretion of the investigator; ‡Dose reduced if self-monitored plasma glucose (SMPG) <4.4 mmol/l (<80 mg/dl) or occurrence of ≥2 symptomatic or 1 severe hypoglycaemic episode in the preceding week

SMPG, self-monitored plasma glucose; T2DM, type 2 diabetes mellitus

Russell-Jones D, et al. Diabetes Obes Metab. 2019;21:1615–24.

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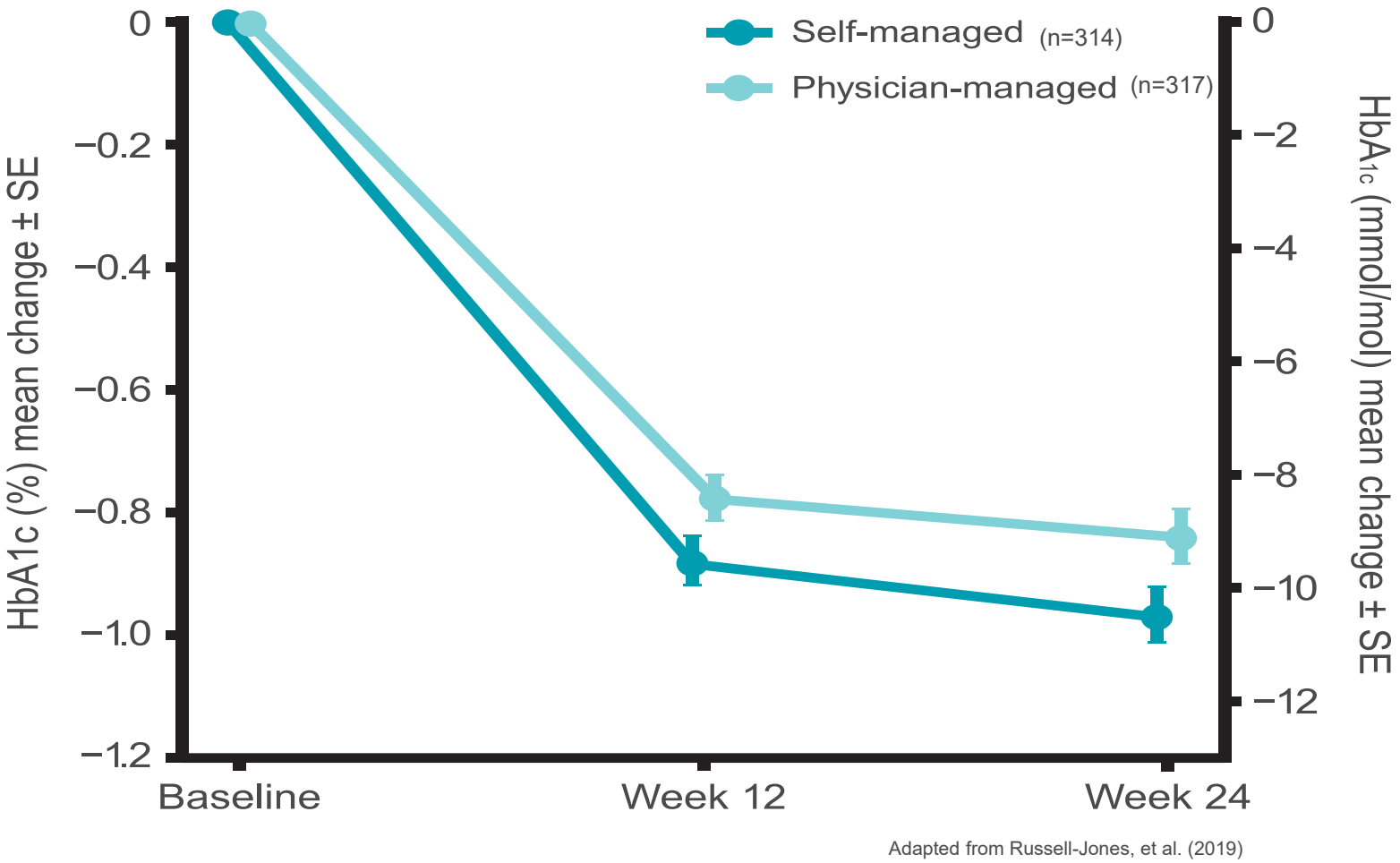
Patient self-titration with Toujeo® resulted in a greater reduction in HbA1c vs physician-led titration at 24 weeks

HbA_{1c} reduction between baseline and Week 24



Adapted from Russell-Jones, et al. (2019)

At week 24, the least squares (LS) mean HbA1c reduction was:

- **self-managed group -0.97%** (10.6 mmol/mol)
- **physician-managed group -0.84%** (9.2 mmol/mol)

LS mean difference −0.13
(95% CI: −0.2619; −0.0004)

p<0.0001 (non-inferiority)
p=0.0247 (superiority)

Russell-Jones D, et al. Diabetes Obes Metab. 2019;21:1615–24.

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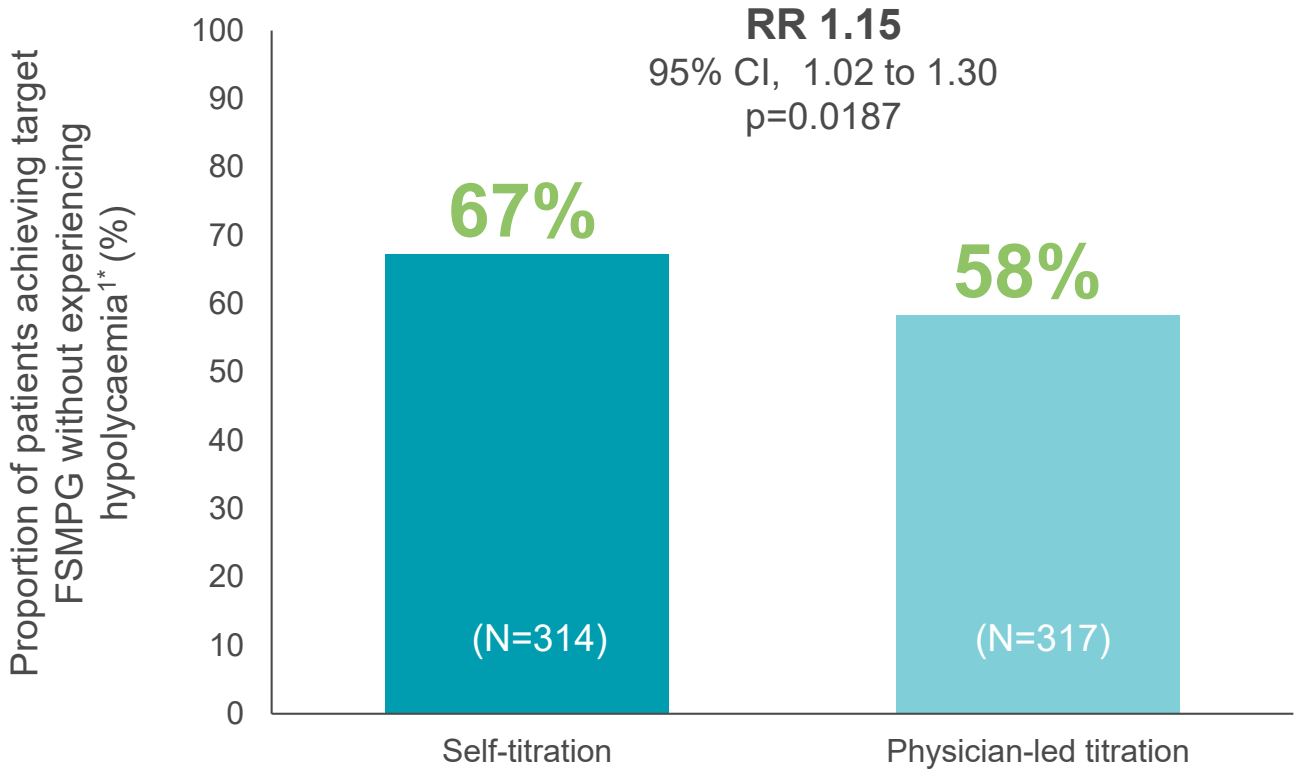
More of the self- than physician-managed group achieved SMPG target without hypoglycaemia at 24 weeks

SMPG target achievement without hypoglycaemia*



*Proportion of patients achieving target fasting self SMPG 4.4-7.2 mmol/L, without severe and/or confirmed (<3.0 mmol/L) hypoglycaemia

Russell-Jones D, et al. Diabetes Obes Metab. 2019;21:1615–24.

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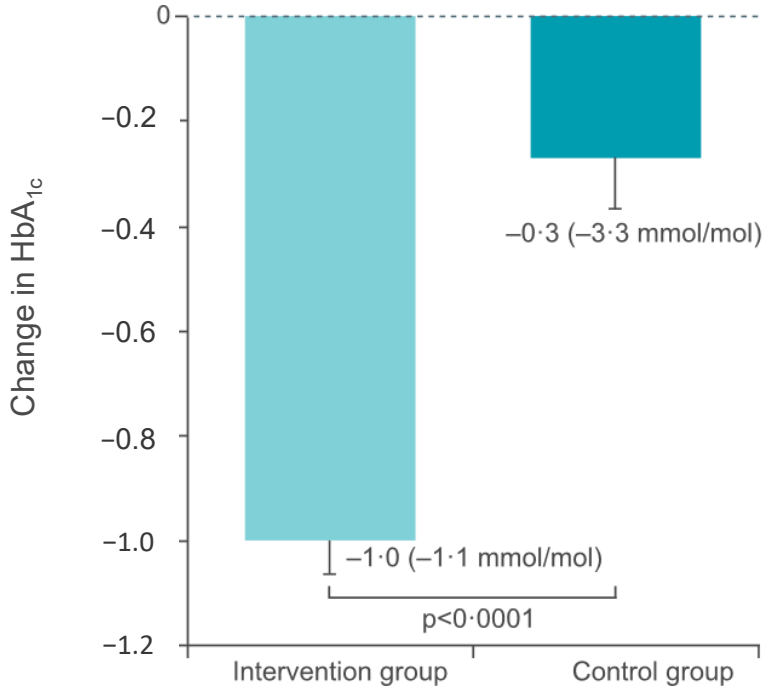
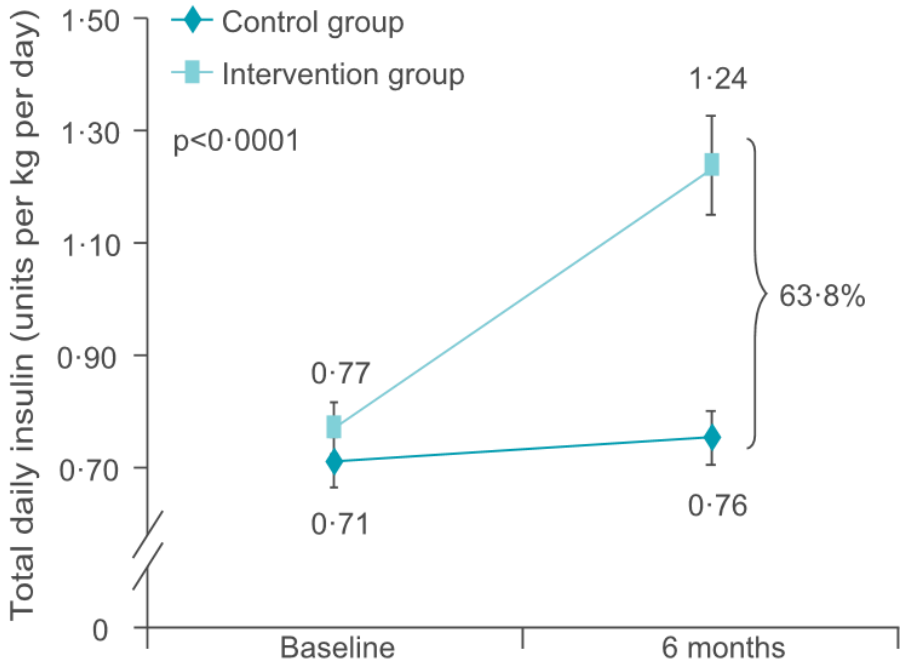
Automated insulin titration guidance with HCP support may lead to improved glycaemic control and effective titration

Study: Multicentre, randomised controlled study designed to assess whether the combination of automated insulin titration guidance with HCP support is superior to HCP support alone with T2DM (N=181) who has been using insulin regimen for the previous 3 months





Adapted from Bergenstal, et al. (2019)

Frequent insulin titration is a key factor in effective insulin therapy and titration support tools need to be evaluated across large healthcare systems

HCP, healthcare professional

Bergenstal RM, et al. Lancet 2019; 393: 1138–48

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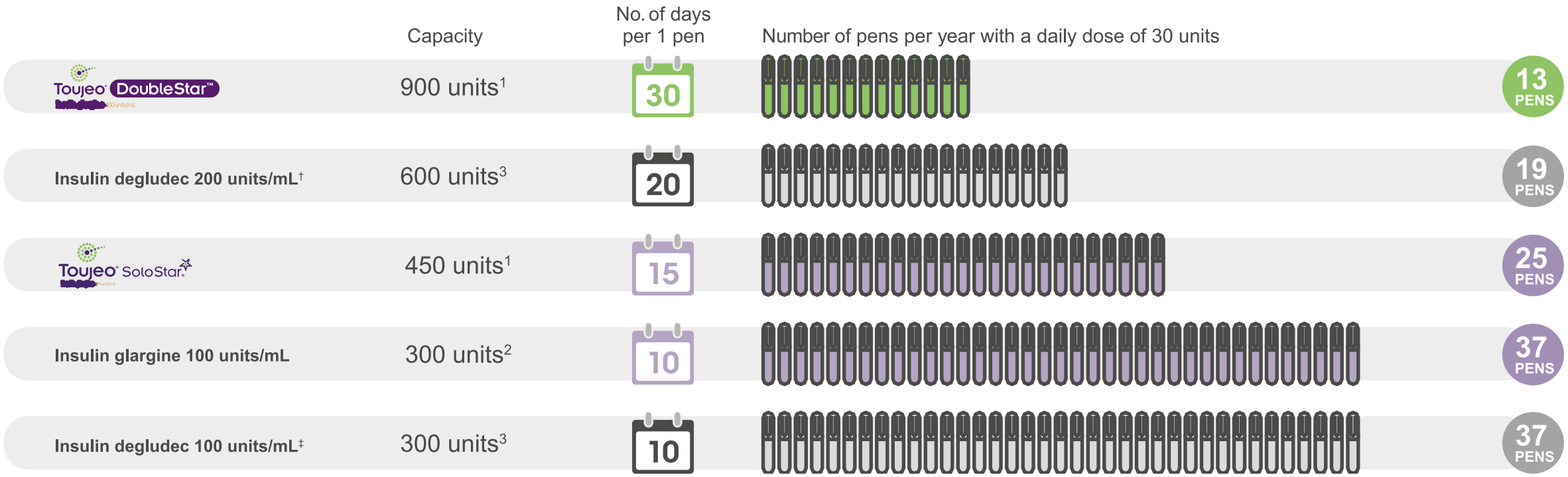
Toujeo® DoubleStar—the highest unit capacity basal insulin pen on the market[1-5]

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 does not take into account any clinical differences in dosing that may be needed with these insulins to get the same effect.

1. Toujeo Summary of Product Characteristics. **2.** Lantus (insulin glargine 100U/mL) Summary of Product Characteristics. **3.** Tresiba Summary of Product Characteristics.. **4.** Levemir Summary of Product Characteristics. **5.** Singh R, et al. Eur Endocrinol. 2018;14;47–51.

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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®
insulin glargine 300 units/mL

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

Toujeo® DoubleStar™
insulin glargine 300 units/mL

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

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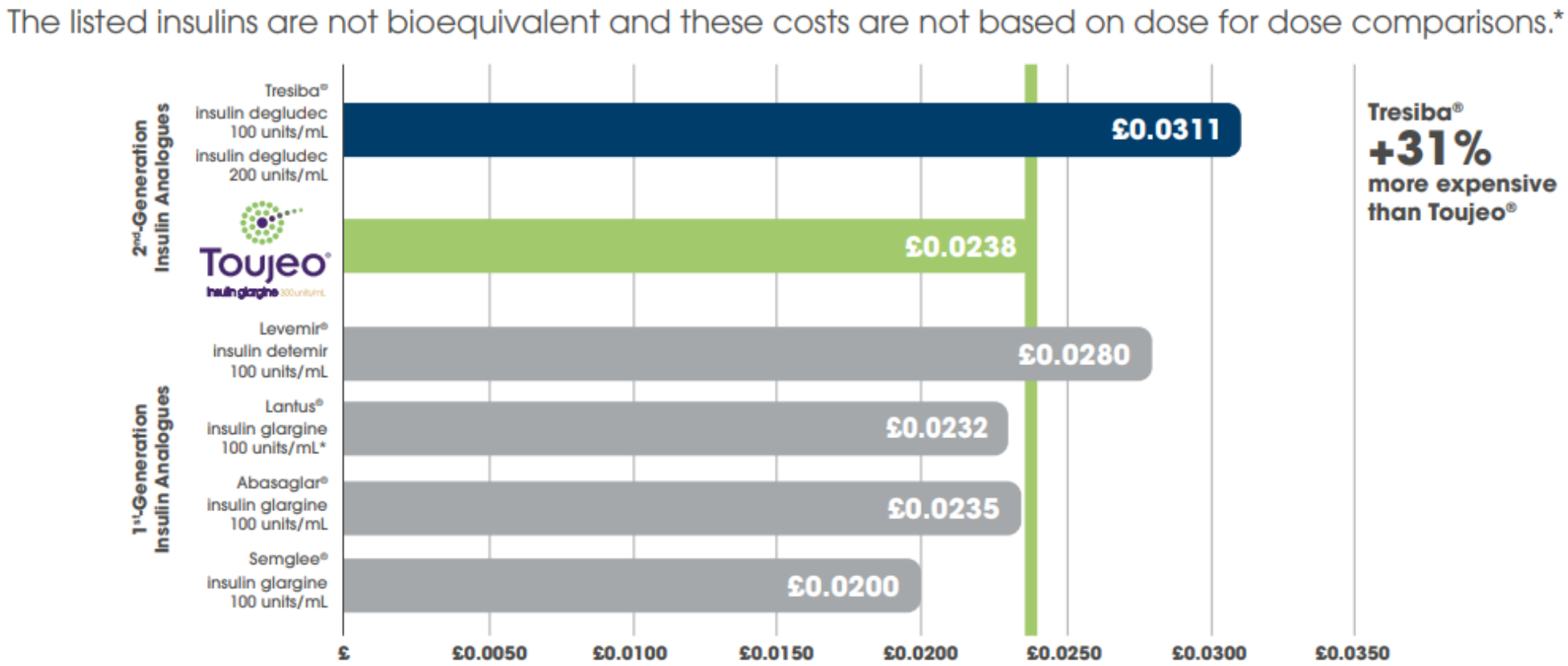
Long-acting insulin acquisition costs—price per unit[1-3]

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].**

1. All prices from BNF https://bnf.nice.org.uk/. [Accessed: November 2024]. 2. Toujeo® Summary of Product Characteristics. 3. Rosenstock J, *et al. Diabetes Care.* 2018;41:2147–2154.

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The clinical evidence and support when starting insulin

EFFICACY

vs insulin glargine 100 U/mL:

- Greater HbA_{1c} reductions with Toujeo® at 12 months[4]

vs insulin degludec 100U/mL:

- Comparable and effective HbA_{1c} reduction with Toujeo® at 6 months[1,2]

SAFETY PROFILE

vs insulin glargine 100 U/mL:

- Lower risk of hypoglycemia with Toujeo® during the full study period (12 months) [4] and the titration phase[4]

vs insulin degludec 100U/mL:

- Comparable rates of hypoglycaemia with Toujeo® at 24 weeks with lower hypoglycaemia incidence and rate with Toujeo® in the titration phase[2]

SUPPORT

- **Toujeo®** DoubleStar pen
- **Toujeo®** educational materials available on the **dedicated patient website**

ACQUISITION COST*

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

*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. Rosenstock J, et al. Diabetes Care. 2018;41:2147–54. **2.** Cheng A, et al. Diabetes Obes Metab. 2020;22:346–54. 3. Ritzel R. et al. Diabetes Obes Metab.2015;17:859–867. 4. Ritzel R. et al. Diabetes Obes Metab. 2018;20:541–548

sanofi

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

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

Presentation: Toujeo 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 population: 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. Frequency not known: Cutaneous amyloidosis. *Prescribers should consult the SmPC in relation to other adverse reactions.*
Legal Category: POM
List Price and Marketing Authorisation Number(s): SoloStar 3 x 1.5ml pens (PLGB 04425/0817): £32.14 DoubleStar 3 x 3ml pens (PLGB 04425/0818): £64.27 **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: October 2024.

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 solution for injection

NI

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: October 2024.

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

GB

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.

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

NI

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

Presentations: Lantus 100 units/ml solution for injection 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.

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. 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). ***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): 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: September 2024

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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BACK UP

Toujeo®
insulin glargine 300U/mL

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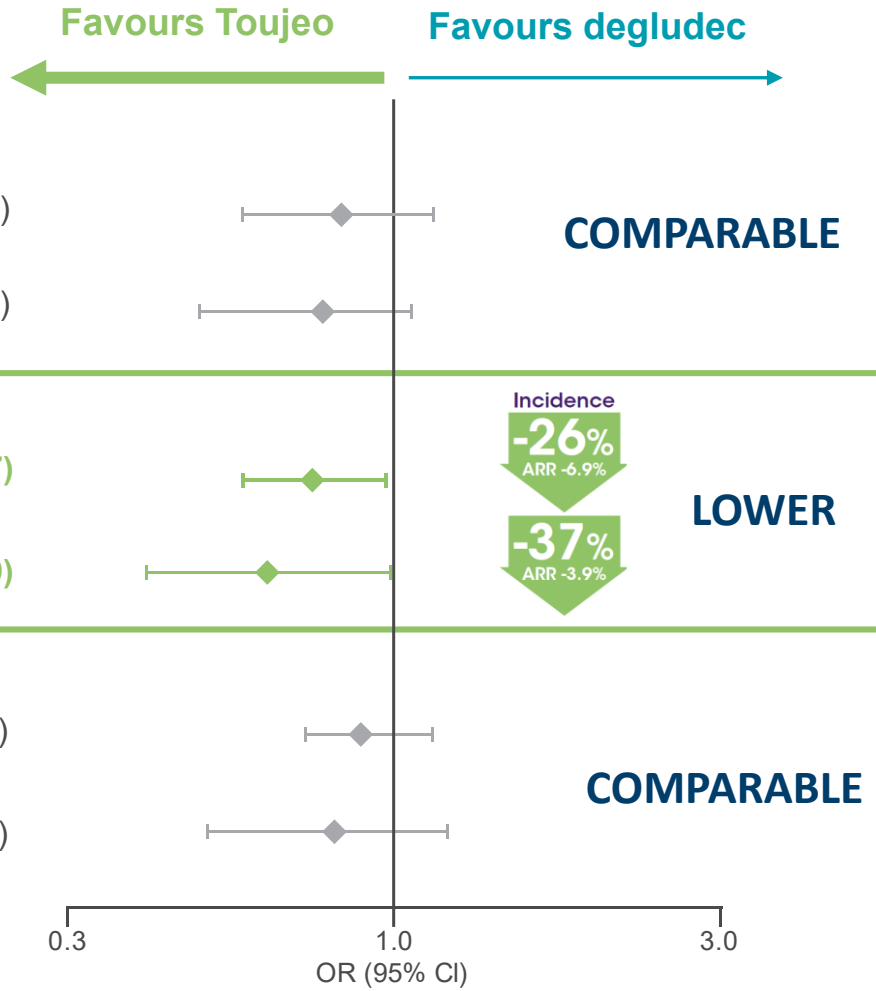
Comparable anytime overall hypoglycaemia, with lower incidence during titration phase

		Incidence (%) Toujeo	Degludec	
Full study period				
24-week period	Confirmed (≤3.9 mmol/L)	66.5	69.0	OR 0.88 (95% CI, 0.66 to 1.17)
	Confirmed (<3.0 mmol/L)	14.7	18.4	OR 0.76 (95% CI, 0.53 to 1.08)
Titration period				
0–12 weeks	**Confirmed (≤3.9 mmol/L)**	47.4	54.3	**OR 0.74 (95% CI, 0.57 to 0.97)**
	Confirmed (<3.0 mmol/L)	7.8	11.7	**OR 0.63 (95% CI, 0.40 to 0.99)**
Maintenance period				
13–24 weeks	Confirmed (≤3.9 mmol/L)	54.1	55.8	OR 0.93 (95% CI, 0.72 to 1.22)
	Confirmed (<3.0 mmol/L)	9.8	11.2	OR 0.86 (95% CI, 0.56 to 1.33)



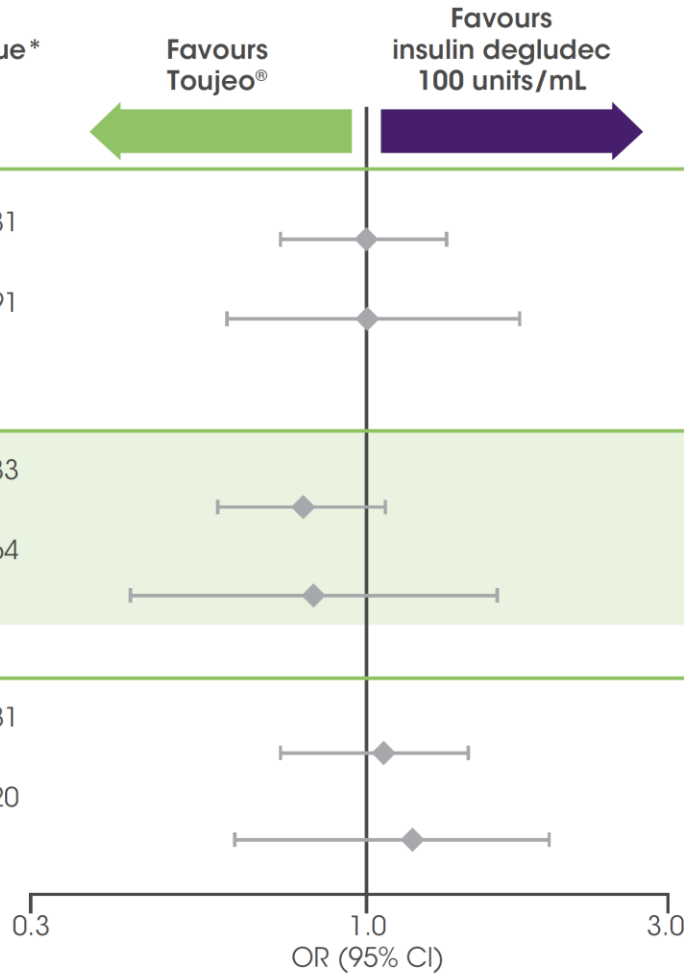
Adapted from Rosenstock J, et al. (2018)

OR, odds ratio; CI, confidence interval, degludec, insulin degludec 100 units/mL

Rosenstock J, et al. Diabetes Care. 2018;41:2147–54.

Comparable nocturnal overall hypoglycaemia, with numerically lower incidence during titration phase

	Incidence %			
	Toujeo®	Insulin degludec 100 units/mL	OR (95% CI)	*p*-value*
Full study period (0–24 weeks)				
Confirmed (≤3.9 mmol/L)	28.6	28.8	0.99 (0.74 to 1.32)	0.931
Confirmed (<3.0 mmol/L)	6.1	6.1	1.00 (0.58 to 1.72)	0.991
Titration period (0–12 weeks)				
Confirmed (≤3.9 mmol/L)	15.2	18.8	0.77 (0.54 to 1.08)	0.133
Confirmed (<3.0 mmol/L)	2.8	3.5	0.80 (0.38 to 1.69)	0.564
Maintenance period (13–24 weeks)				
Confirmed (≤3.9 mmol/L)	21.4	21.0	1.03 (0.74 to 1.42)	0.881
Confirmed (<3.0 mmol/L)	4.5	3.8	1.18 (0.61 to 2.29)	0.620



Adapted from Rosenstock J, et al. (2018)

*All p-values are analysed as nominal.

RR, relative risk; CI, confidence interval, degludec, insulin degludec 100 units/mL

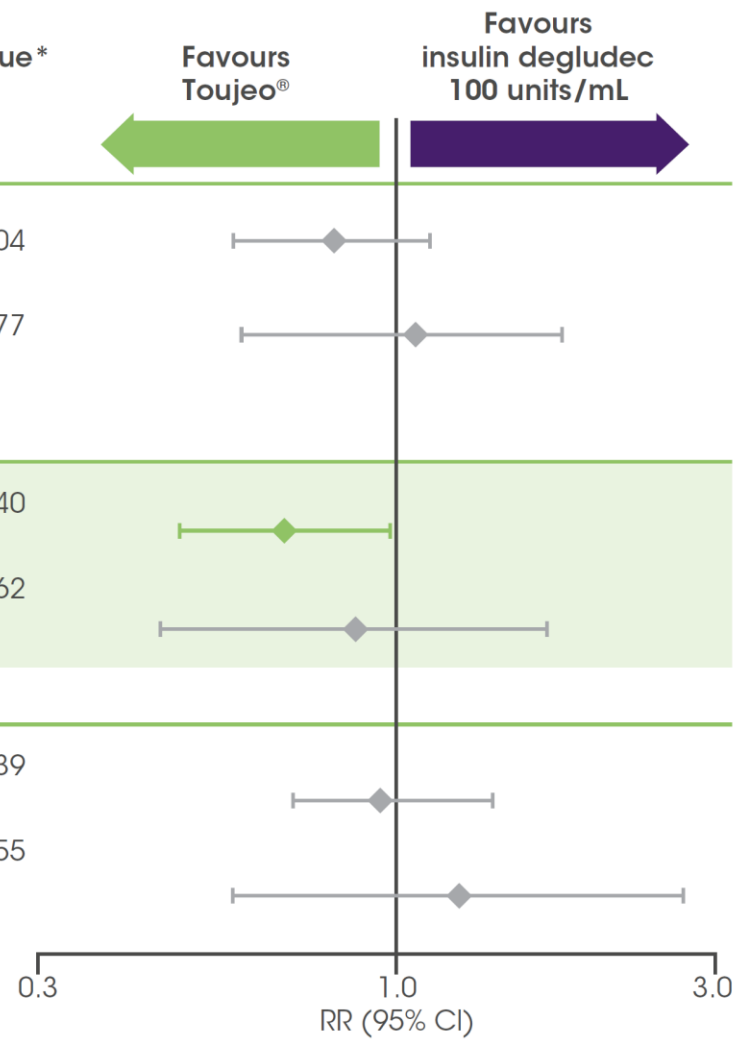
Rosenstock J, et al. Diabetes Care. 2018;41:2147–54.

Comparable nocturnal overall hypoglycaemia, with lower rate during titration phase

BRIGHT

Event rates per patient-year

	Toujeo®	Insulin degludec 100 units/mL	RR (95% CI)	*p*-value*
Full study period (0–24 weeks)				
Confirmed (≤3.9 mmol/L)	1.83	2.26	0.81 (0.58 to 1.12)	0.204
Confirmed (<3.0 mmol/L)	0.24	0.22	1.09 (0.60 to 2.00)	0.777
Titration period (0–12 weeks)				
Confirmed (≤3.9 mmol/L)	1.42	2.20	0.65 (0.43 to 0.98)	0.040
Confirmed (<3.0 mmol/L)	0.16	0.19	0.85 (0.40 to 1.79)	0.662
Maintenance period (13–24 weeks)				
Confirmed (≤3.9 mmol/L)	2.24	2.33	0.96 (0.66 to 1.40)	0.839
Confirmed (<3.0 mmol/L)	0.33	0.26	1.27 (0.57 to 2.83)	0.555



Event rates
- 35%
ARR -0.8

Adapted from Rosenstock J, et al. (2018)

*All p-values are analysed as nominal.

RR, relative risk; CI, confidence interval, degludec, insulin degludec 100 units/mL

Rosenstock J, et al. Diabetes Care. 2018;41:2147–54.

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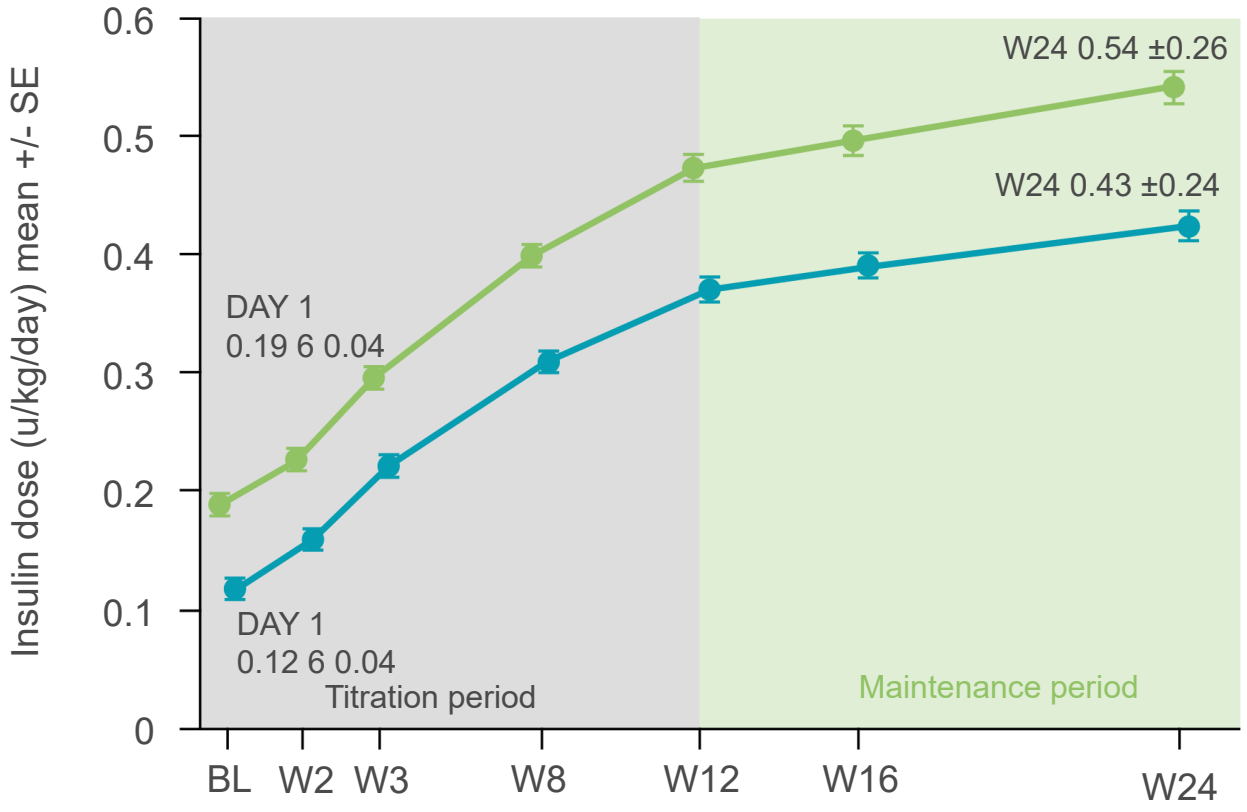
BRIGHT: Toujeo vs insulin degludec 100 units/mL for 24 weeks

Insulin dose adjustment was to a target fasting SMPG

Insulin dose change over 24 weeks



SE, standard error; W, week, SMPG, self-monitored plasma glucose

Adapted from Rosenstock J, et al. (2018)

Mean body weight increase at week 24
Toujeo: 2.0 +/- 3.8 kg
Degludec: 2.3 +/- 3.6 kg

LS mean difference in body weight change
Toujeo vs insulin degludec 100 U/mL
−0.33 kg (95% CI -0.81 to 0.15)

Despite the difference in insulin dose at Week 24, bodyweight gains and the rates of hypoglycaemia at Week 24 were similar

Rosenstock J, et al. Diabetes Care. 2018;41:2147–54.