Toujeo® clinical evidence in vulnerable patients

This promotional meeting is organized and funded by Sanofi

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

For Great Britain and Northern Ireland: 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

For Ireland: Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie; email: medsafety@hpra.ie Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com

MAT-GB-2103782 (V4.0) November 2024

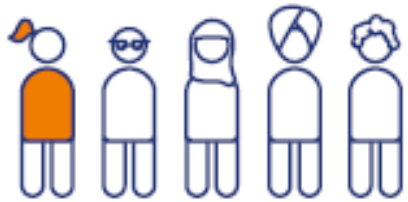
Prescribing information and Adverse event reporting can be found at the end of the presentation.

Diabetes UK - facts and stats

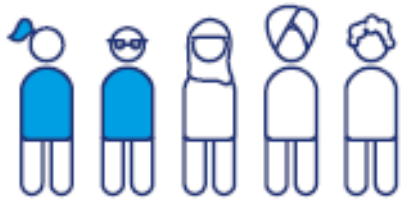
5.6 million
people in UK have **diabetes**[1]

At least 10,350
people in UK have end stage **kidney failure** because of their diabetes[1]

27% and 72%
people in UK with Type 1 and type 2 diabetes respectively are **older than 60-years-old**[3]



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_ accessed November 2024
3. Barron E. et al Lancet Diabetes Endocrinol 2020; 8: 813–22

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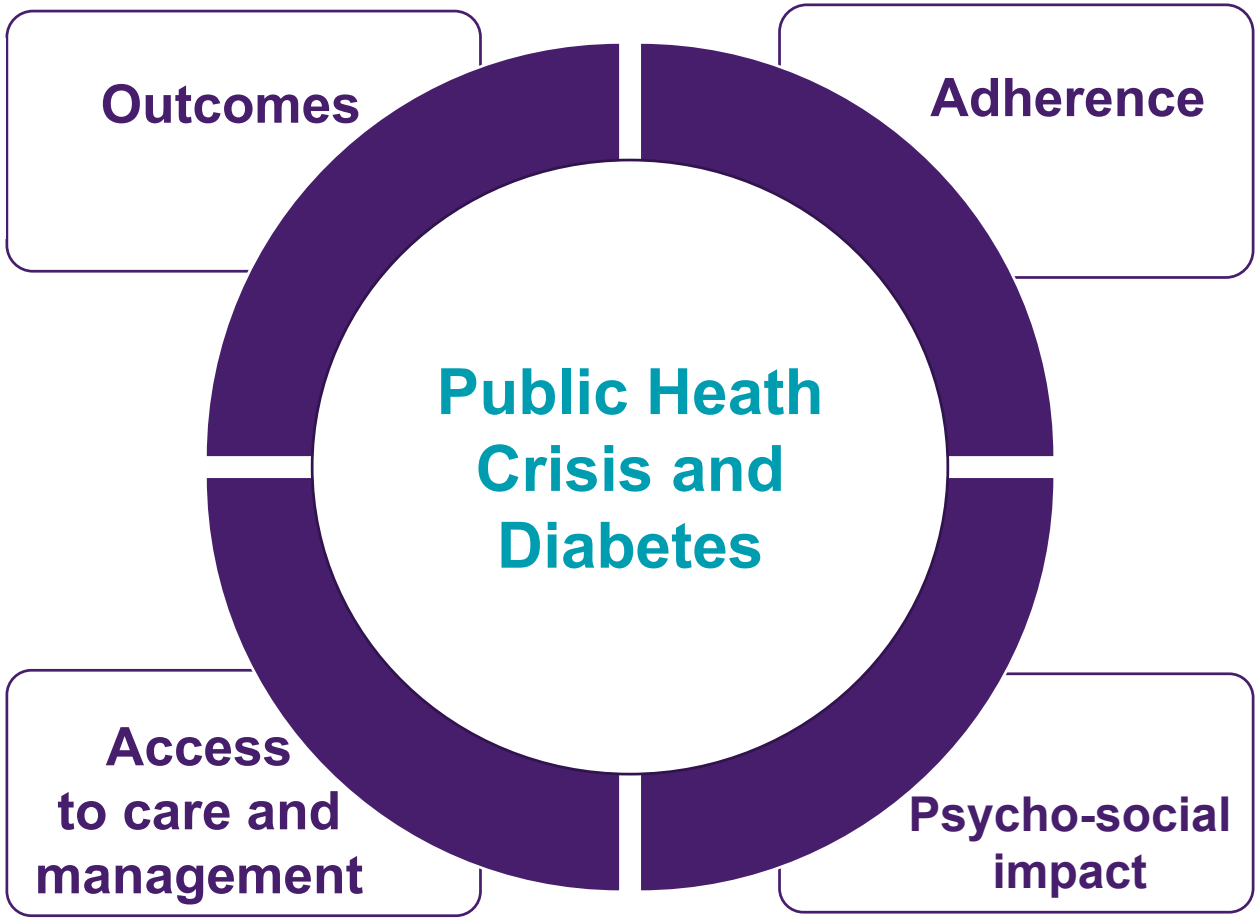
Public health crises pose both direct and indirect risks to people with diabetes

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 Situatios, 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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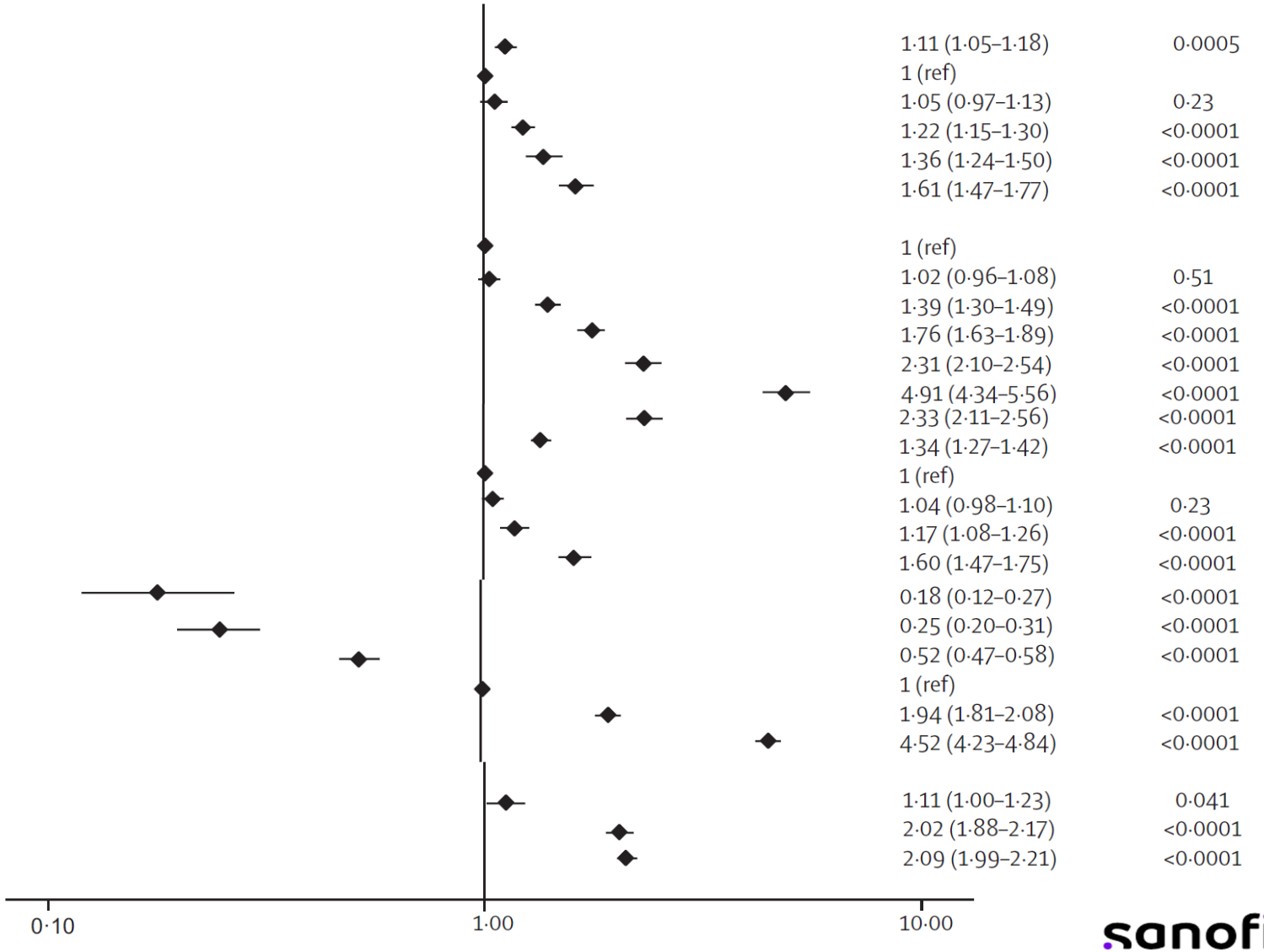
Increased COVID-19-related mortality was not only associated with CV and renal complications of diabetes but also with glycaemic control and BMI

adjusted hazard ratios for COVID-19-related death in people with type 2 diabetes (n=2 874 020) in England up to May 11, 2020



eGFR=estimated glomerular filtration rate

1. . Holman N. et al. Lancet Diabetes Endocrinol 2020; 8: 823–33

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The impact of hypoglycaemia early in basal insulin initiation

Why is the initial basal insulin titration period a critical time for patients?

Future hypoglycaemia risk

Early hypoglycaemia after basal insulin initiation in T2DM is associated with an increase in long-term hypoglycaemia risk (odds ratio 5.71, 95% CI: 4.67–6.99)[1]

Future treatment discontinuation

Early hypoglycaemia after basal insulin initiation in T2DM is associated with an increase risk of treatment discontinuation[2]

The risk of hospitalisation

Early hypoglycaemia after basal insulin initiation in T2DM is associated with an increase the risk of hospitalisation[2]

Impact on quality of life

Experience of hypoglycaemia on basal insulin in T2DM may impairs quality of life[3,4]

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. 4. Ahammed A. et al. Indian J Endocrinol Metab. 2018 Jul-Aug; 22(4): 499–504

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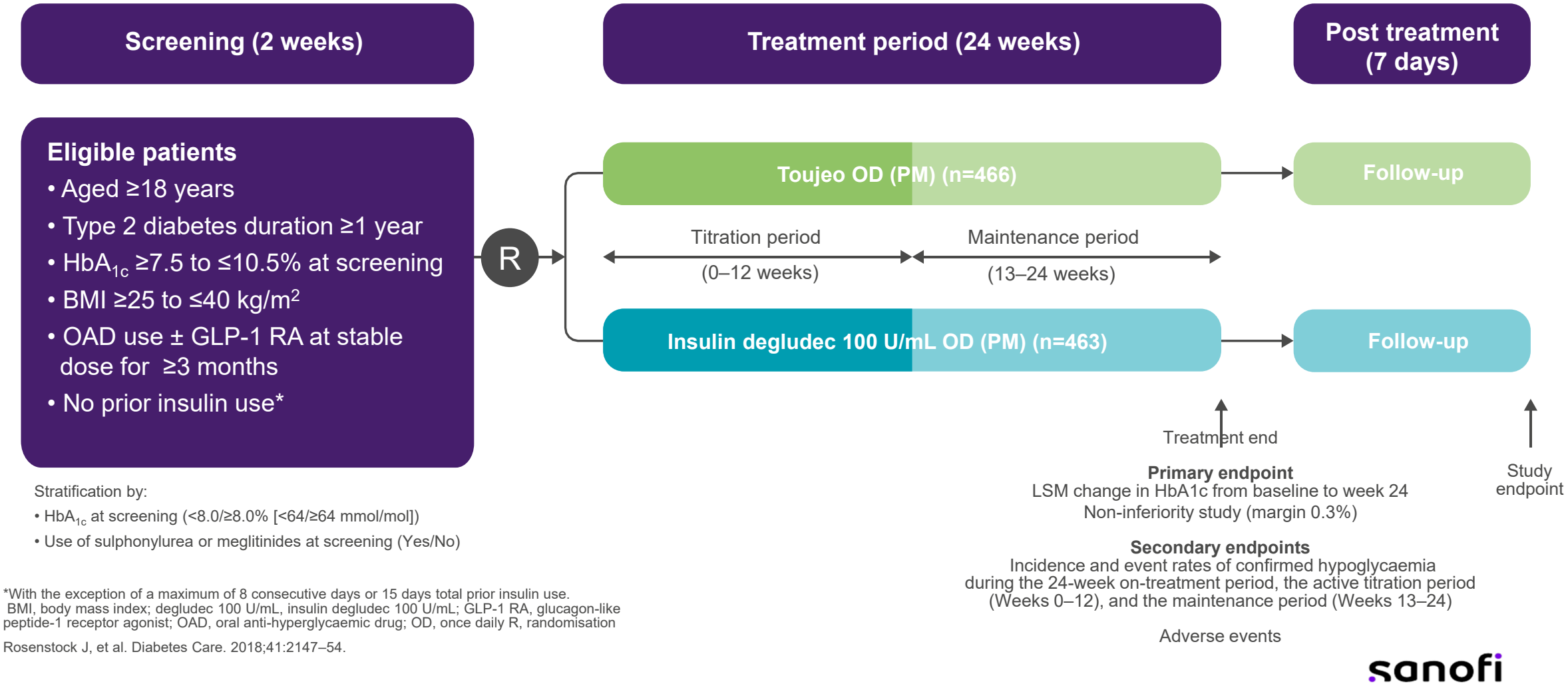
The first head-to-head trial comparing Toujeo® insulin glargine 300 U/mL vs insulin degludec 100 units/mL in people with T2DM

BRIGHT

RCT

Insulin-naïve adults with type 2 diabetes



Stratification by:

- HbA1c at screening (<8.0/≥8.0% [<64/≥64 mmol/mol])
- Use of sulphonylurea or meglitinides at screening (Yes/No)

*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

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

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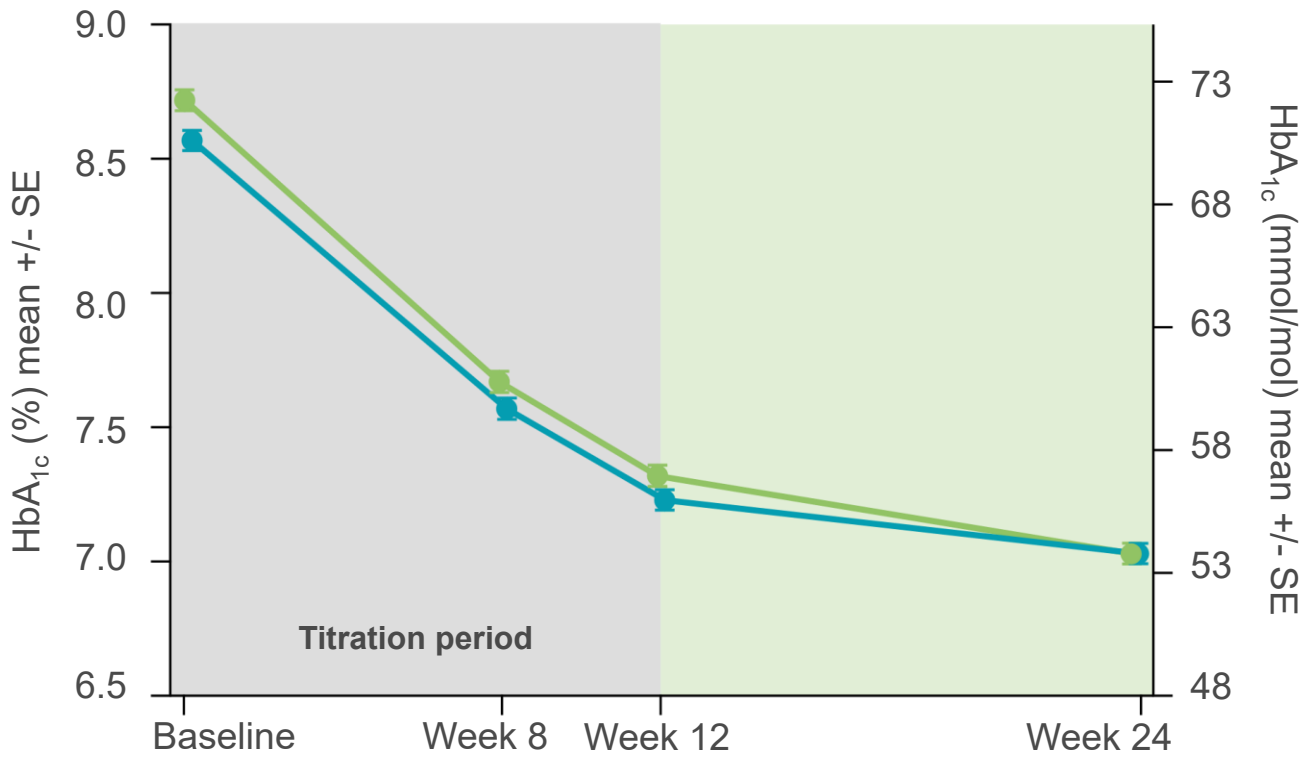
Comparable and effective HbA1c reduction with Toujeo® and insulin degludec 100 units/ mL [1,2]

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% (n=462)	−1.59% (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% (n=448)	−1.39% (n=445)

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

I* HbA_{1c} least squares mean change (± SE)
TT, intention-to-treat, 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.

Explore insulin dose

Comparable anytime overall hypoglycaemia, with lower event rate during the titration phase[1]

BRIGHT

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

COMPARABLE

Full study period

Day 1- Week 24

Toujeo 0.61 vs Degludec 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 0.49 vs Degludec 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 0.73 vs Degludec 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.

Reference: 1 Cheng A, et al. Diabetes Obes Metab. 2020;22:346–54.

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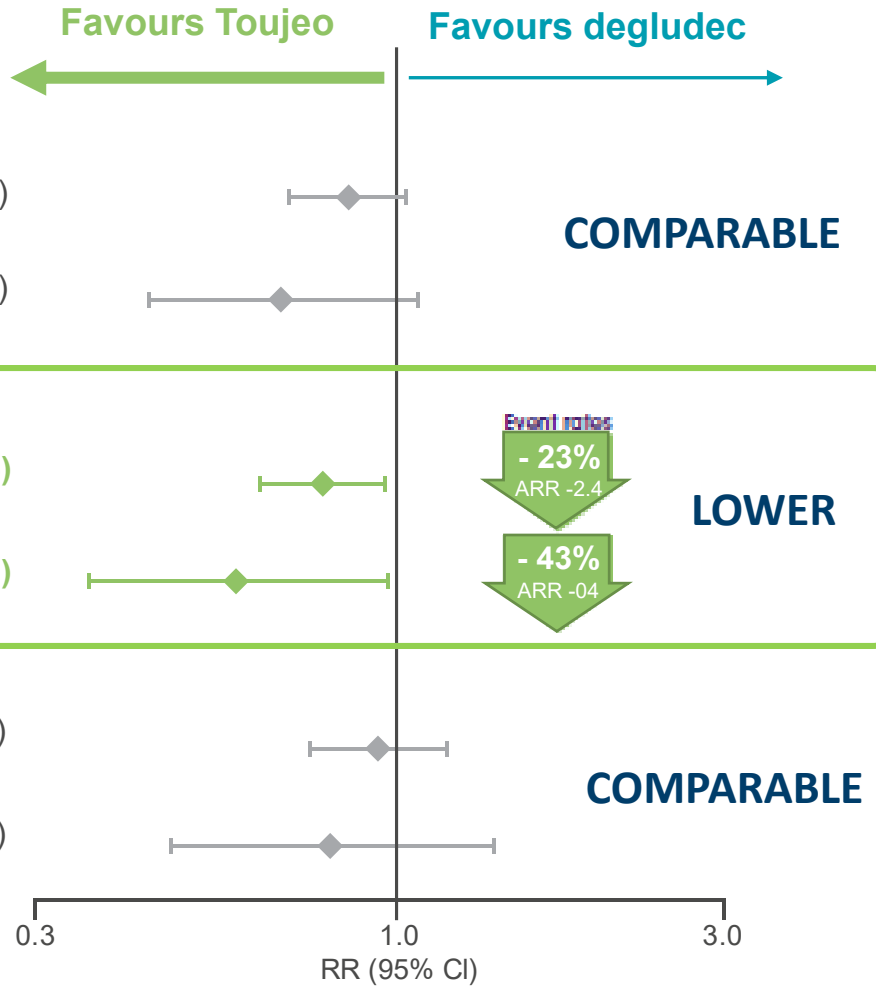
Comparable anytime overall hypoglycaemia, with lower event rate during the titration phase

		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.

Explore anytime hypoglycemic incidence and nocturnal hypoglycemia incidence and rate

BRIGHT subgroup analysis based on eGFR categories[1]

Aim: To examine whether clinical outcomes with Toujeo® and insulin degludec 100 U/ml are affected by renal function

Pre-defined subgroup analysis

Change in HbA1c by renal subgroups

Post-hoc analysis

Change in hypoglycaemia incidence and events rates by renal subgroups

Further investigation is required to confirm the exploratory results in this vulnerable population. No multiplicity adjustments were made. 95% CI's and p-values are provided for descriptive purposes.

Study limitations:

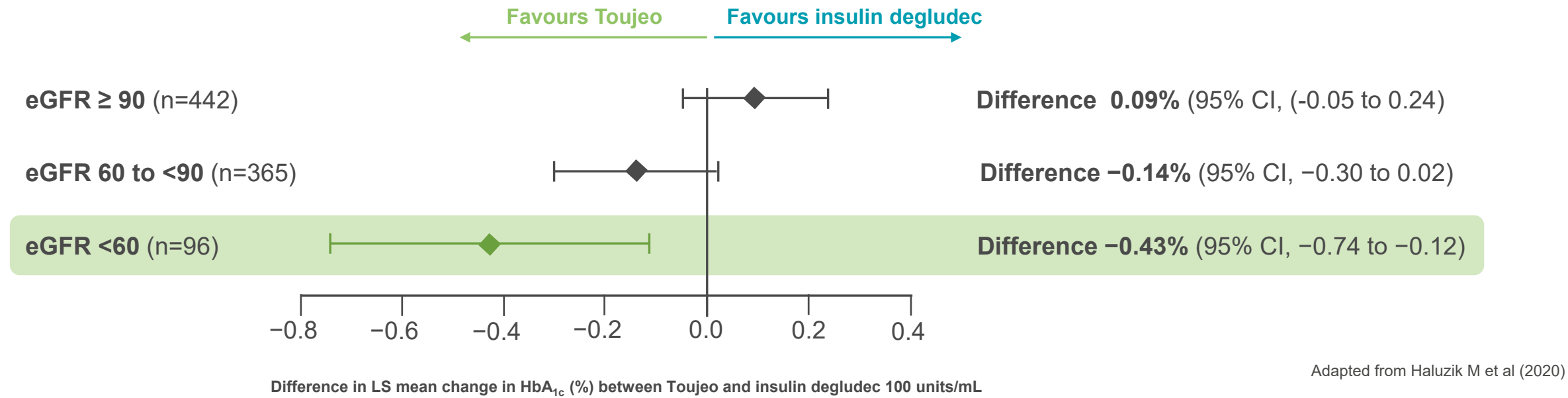
- This subgroup analysis of BRIGHT was not a dedicated prospective trial in people with CKD.
- The number of patients in each subgroup was not controlled, therefore the baseline characteristics may have differed between subgroups
- There were fewer patients in the <60 mL/min/1.73 m_2 group than the ≥90 mL/min/1.73 m_2 group (96 vs 467)

Haluzík M, et al. Diabetes Obes Metab. 2020;22:1369–77.

Heterogeneity of treatment effect across renal function subgroups was observed (p=0.02)

RCT
Sub-group analysis

Change in HbA_{1c} across eGFR (mL/min/1.73 m^2) subgroups from baseline to Week 24



Adapted from Haluzik M et al (2020)

Further investigation is required to confirm the exploratory results in this vulnerable population. No multiplicity adjustments were made. 95% CI's and p-values are provided for descriptive purposes.

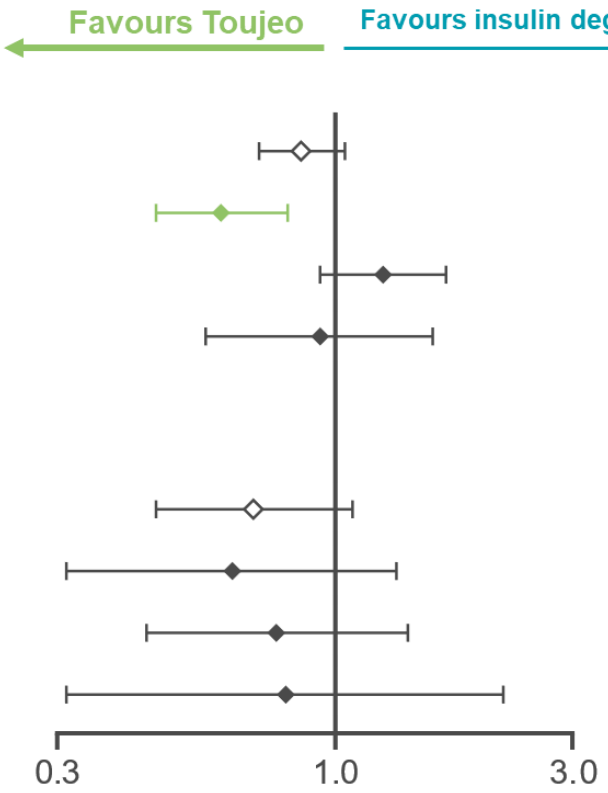
eGFR, estimated glomerular filtration rate

Haluzík M, et al. Diabetes Obes Metab. 2020;22:1369–77.

Event rate of anytime confirmed hypoglycaemia across renal function subgroups

RCT
Sub-group analysis

Baseline	Events/pt-year Toujeo	Degludec	RR (95% CI)
Event rate of ≤3.9 mmol/L			
Overall	9.34	10.83	0.86 (0.71 to 1.04)
eGFR ≥ 90	6.49	10.45	0.60 (0.45 to 0.81)
eGFR 60 to <90	12.25	10.52	1.23 (0.93 to 1.64)
eGFR <60	13.53	13.87	0.93 (0.56 to 1.54)
Event rate of <3.0 mmol/L			
Overall	0.61	0.88	0.69 (0.45 to 1.08)
eGFR ≥ 90	0.37	0.57	0.63 (0.30 to 1.31)
eGFR 60 to <90	0.80	1.12	0.77 (0.43 to 1.38)
eGFR <60	1.18	1.39	0.80 (0.30 to 2.11)



Adapted from Haluzik M et al (2020)

Further investigation is required to confirm the exploratory results from the in this vulnerable population. No multiplicity adjustments were made. 95% CI's and p-values are provided for descriptive purposes.

RR, rate ratio; CI, confidence interval

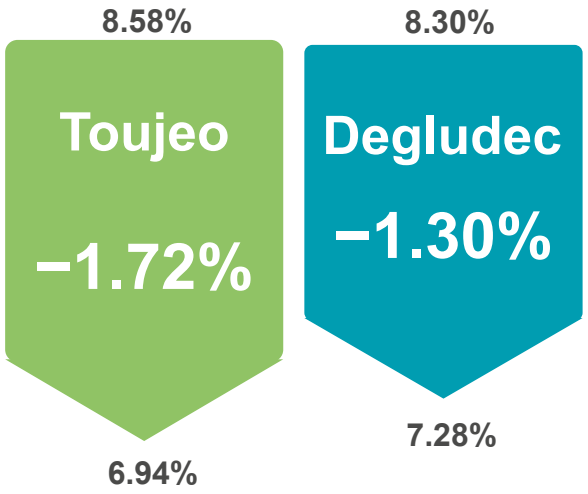
Haluzík M, et al. Diabetes Obes Metab. 2020;22:1369–77.

Observed HbA1c differences did not compromise hypoglycaemia within the subgroup eGFR, <60 mL/min/1.73 m2

RCT
Sub-group analysis

Pre-defined primary analysis

LSM difference in HbA1c change −0.43%
(95% CI, −0.74 to −0.12)*



***Post hoc* analysis**

Anytime (24 h) confirmed (≤3.9 mmol/L) hypoglycaemia rate
Events/patient-year

Toujeo	vs	Degludec
13.5		13.9

RR (95% CI): 0.93 (0.56 to 1.54)**

No difference

Further investigation is required to confirm the exploratory results from the in this vulnerable population. No multiplicity adjustments were made. 95% CI's and p-values are provided for descriptive purposes.

*LSM data and 95% CI derived from a MMRM approach **Rate ratios and CIs are based on an over-dispersed Poisson regression model.
CI, confidence interval; eGFR, estimated glomerular filtration rate in mL/min/1.73 m^2; LSM, least squares mean; MMRM, mixed models for repeat measurement; RR, rate ratio

Haluzík M, et al. Diabetes Obes Metab. 2020;22:1369–77.

Toujeo vs first-generation standard of care basal insulin in insulin naïve T2DM patients Impact of renal function in the ACHIEVE Control Study*

EASD 2020

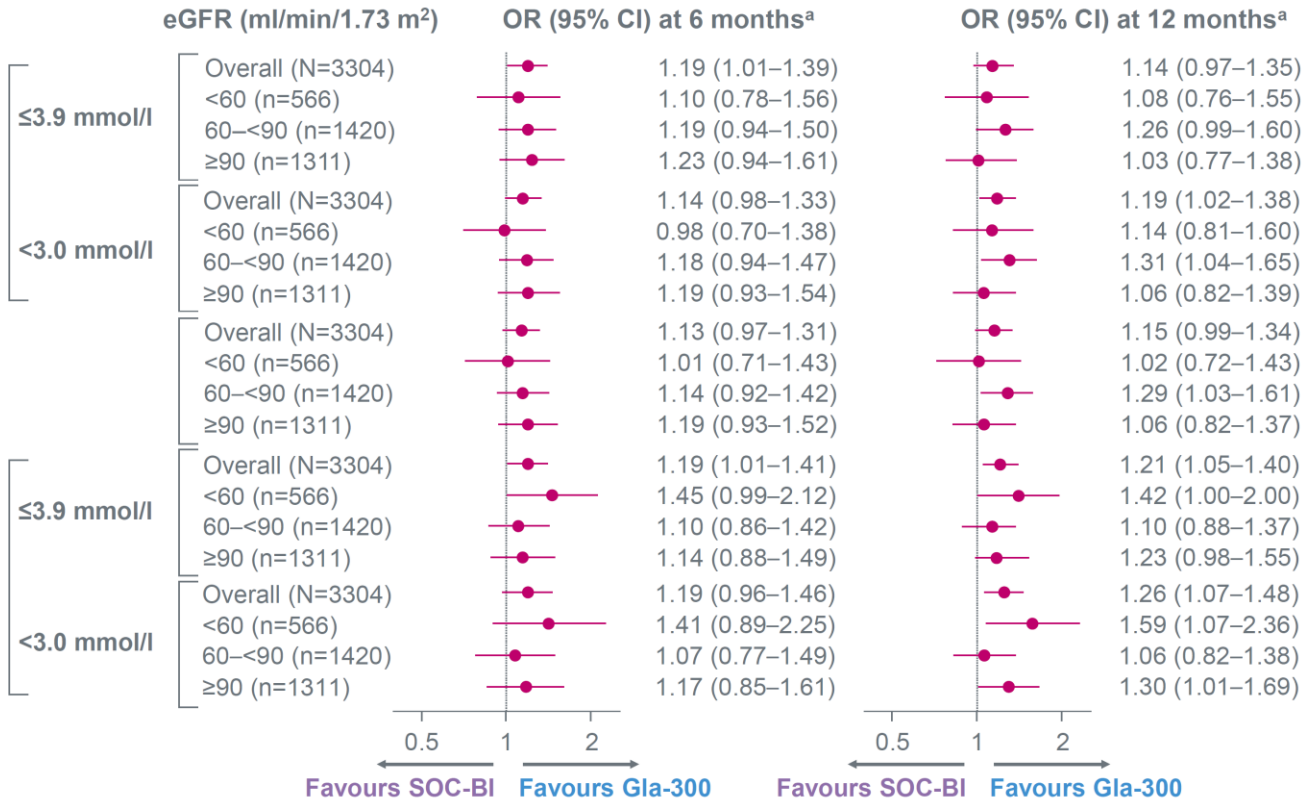
Observational study
Post-hoc analysis

Toujeo demonstrated **superiority compared with first-generation SOC-BI** in the primary composite endpoint of reaching individualised HbA1c targets without hypoglycaemia at 6 months

Composite endpoint
Attainment of individualised HEDIS HbA1c targets without documented symptomatic hypoglycaemia(BG ≤3.9 mmol/l and <3.0 mmol/l) or severe hypoglycaemia[b,c]

HbA1c target attainment
Attainment of individualized HbA1c targets per HEDIS criteria[c]

Without hypoglycaemia
No documented symptomatic hypoglycaemia (BG ≤3.9 mmol/l and <3.0 mmol/l) or severe hypoglycaemia [d]



Within eGRF subgroups

clinical outcomes of composite endpoint were consistent with or trended with those in the overall study population

These results are hypothesis-generating and warrant further evaluation in prospective studies

ACHIEVE Control (NCT02451137) was a real-life, multicentre, randomised, open-label, active-controlled, 2-arm, parallel-group, pragmatic trial in insulin-naive adult uncontrolled (HbA1c 8−11%) people with T2D. a) Based on a logistic regression model with treatment arm as fixed effect and adjusting for HbA1c target (<7% or <8%), sulphonylureause, GLP-1 RA use, and baseline HbA1c (continuous variable); b) HbA1c target attainment without hypoglycaemia; c) TheHbA1c target was <8.0% for participants ≥65 years of age or with defined comorbidities, and <7.0% for all other participants; d) Defined as documented symptomatic (≤3.9 mmol/l or <3.0 mmol/l) or severe hypoglycaemia at any time of day

Meneghini L. et al. EASD - Poster 671

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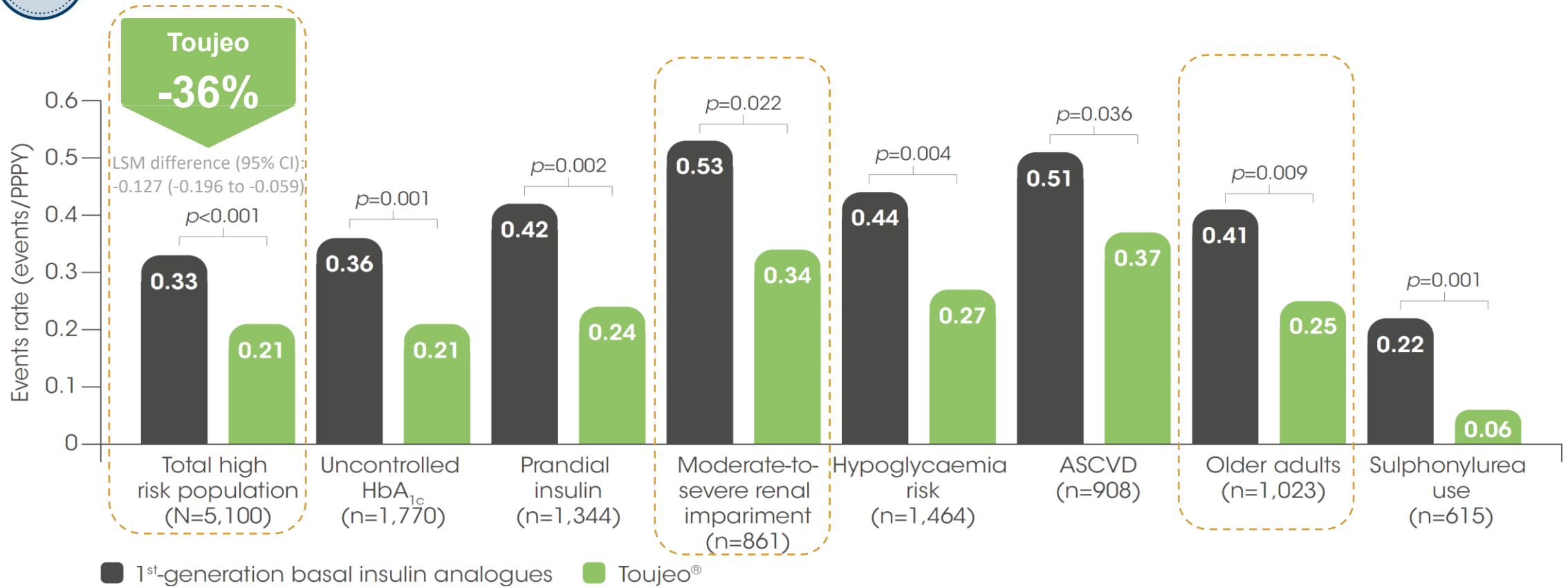
Significantly lower hypoglycaemia associated with hospitalisation and Emergency Department visits vs 1st-generation basal insulin analogues across high risk T2DM patient subgroups

DELIVER

Retrospective cohort study

Event rate (events/PPPY) of hypoglycaemia associated with hospitalisation/ED visit at 12 months



Retrospective cohort study of 5,100 people with T2DM at high risk of hypoglycaemia who switched from a 1st-generation basal insulin analogue to either Toujeo or another 1st-generation basal insulin analogue.

High risk defined as: patients aged >64 years; basal-bolus insulin use; renal impairment (eGFR 30–59 mL/min/1.73 m2); uncontrolled baseline HbA1c; sulphonylurea use; atherosclerotic cardiovascular disease; history indicating high risk, including ≥1 severe hypoglycaemic episode (prior 12 months).

CI, confidence interval; ED, emergency department; HbA1c, glycated haemoglobin; LSM, least squares mean; PPPY, per person per year; T2DM, type 2 diabetes mellitus.

Sullivan SD, et al. Presented at the 79th Scientific Sessions of the American Diabetes Association 2019; June 7–11; San Francisco, CA, US. 133-LB.

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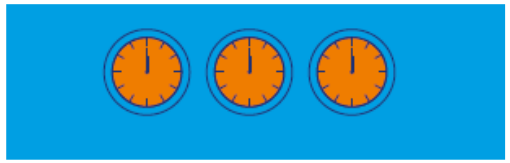
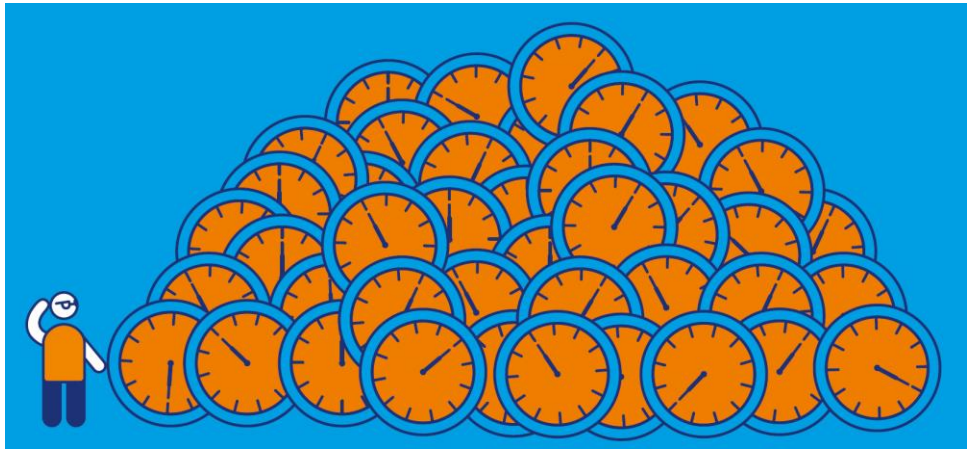
Managing Diabetes

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

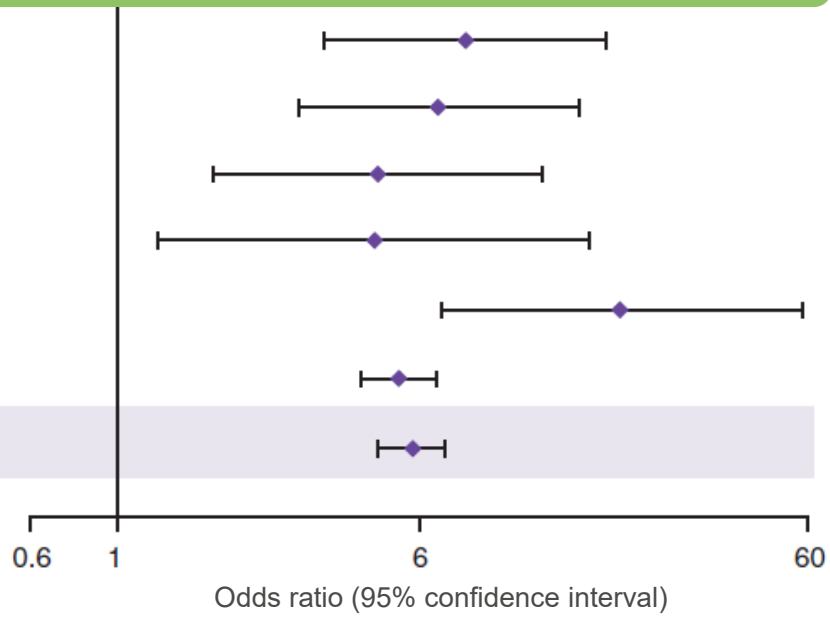
BACK UP slides

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

Hypoglycaemia during the initial 3 months after insulin initiation was **predictive of hypoglycaemia risk over the ensuing 3 to 24 months**

~5.7x

more likely to have hypoglycaemia at 24 months

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.

The risk of future hypoglycaemia (at 24 months) was greater if hypoglycaemia was experienced in the first 3 months (OR, 5.71, 95% CI: 4.67–6.99).

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

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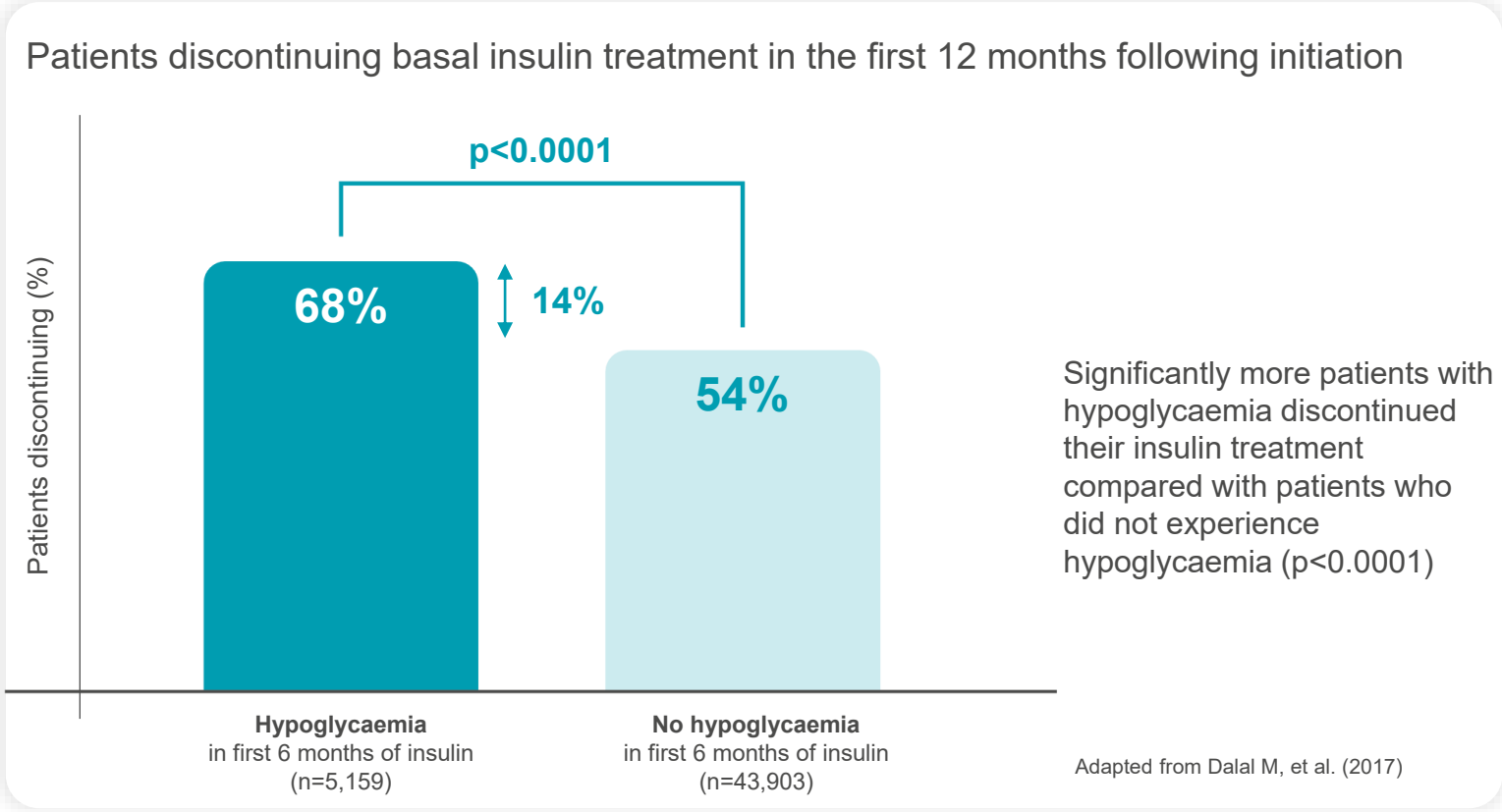
Early hypoglycaemia increases the risk of treatment discontinuation

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)

- A retrospective cohort study of patient-level data using electronic medical records
- Adult patients initiating basal insulin glargine, insulin detemir, or NPH between Jan 2008 and March 2014
- 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 the index date
- With hypoglycaemia and without hypoglycaemia cohorts were compared for basal insulin treatment discontinuation

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

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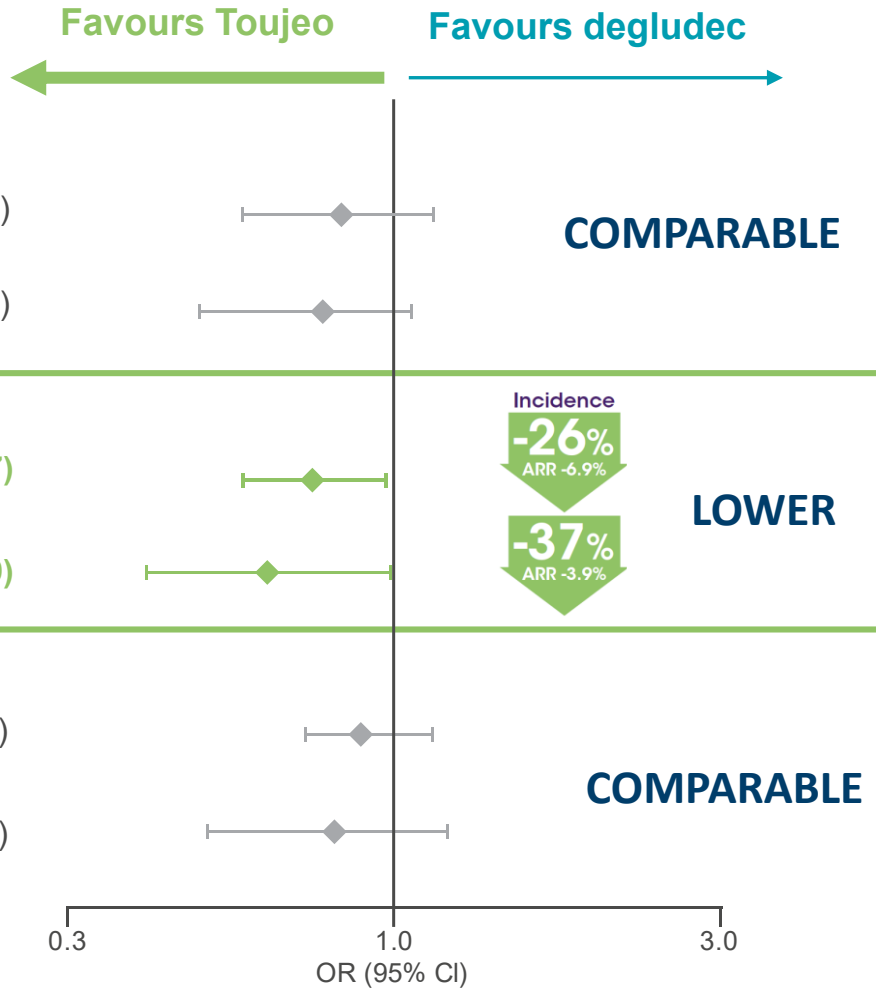
Comparable anytime overall hypoglycaemia, with lower incidence during titration phase

		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)

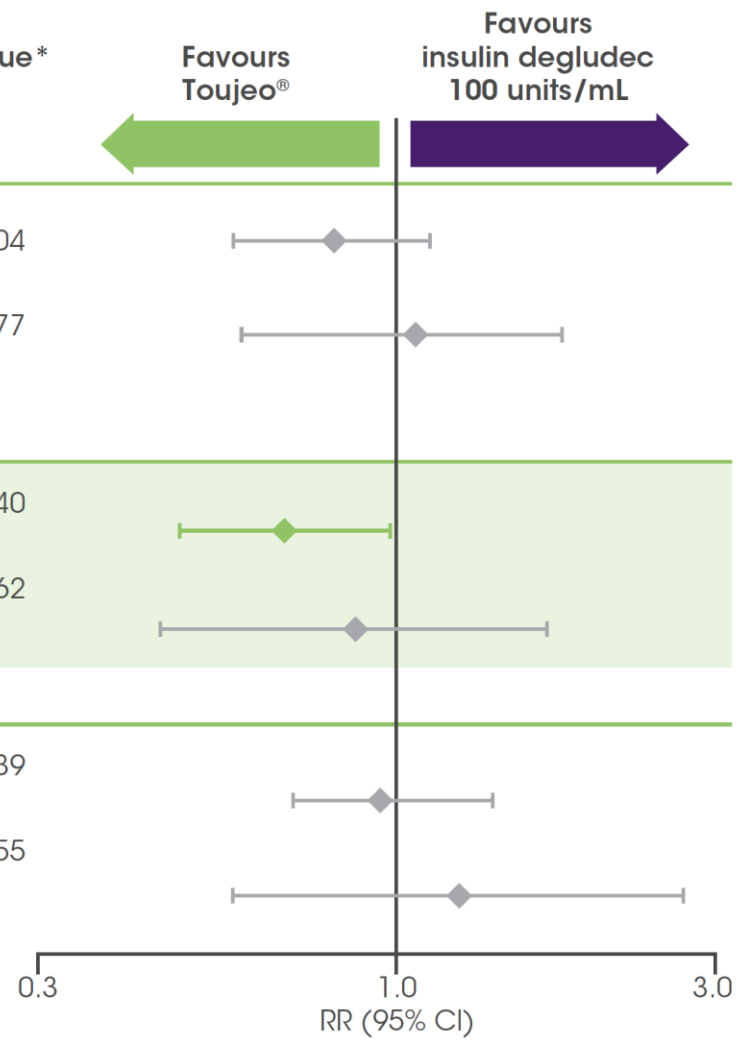
OR, odds ratio; CI, confidence interval, degludec, insulin degludec 100 units/mL

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

Back to anytime hypoglycaemia rate

Comparable nocturnal overall hypoglycaemia, with lower rate during titration phase

	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.

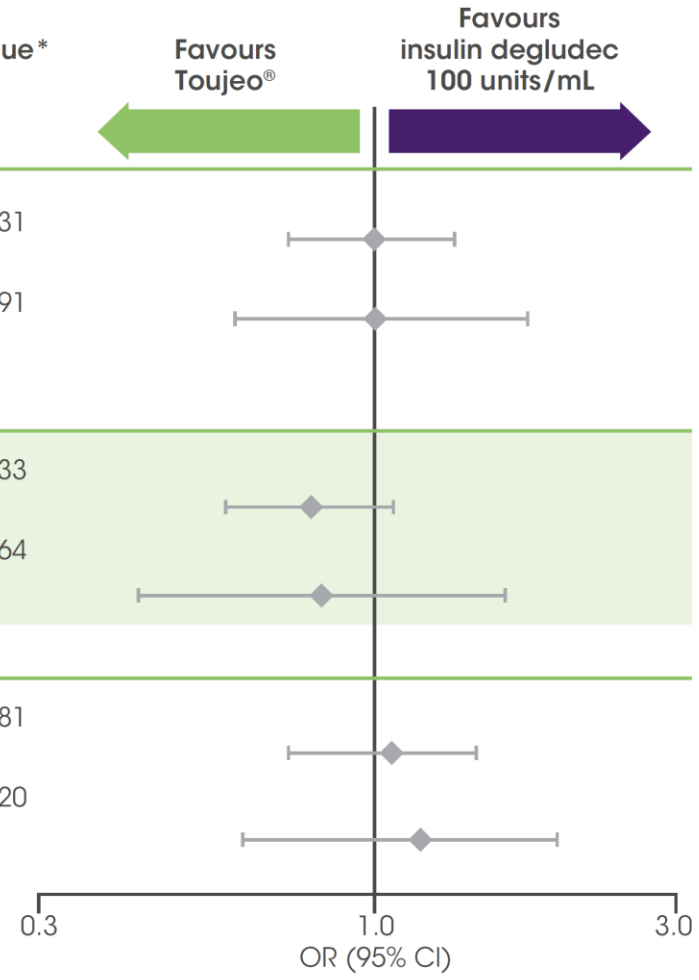
RR, relative risk; CI, confidence interval, degludec, insulin degludec 100 units/mL

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

Back to anytime hypoglycaemia rate

Comparable nocturnal overall hypoglycaemia, with 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

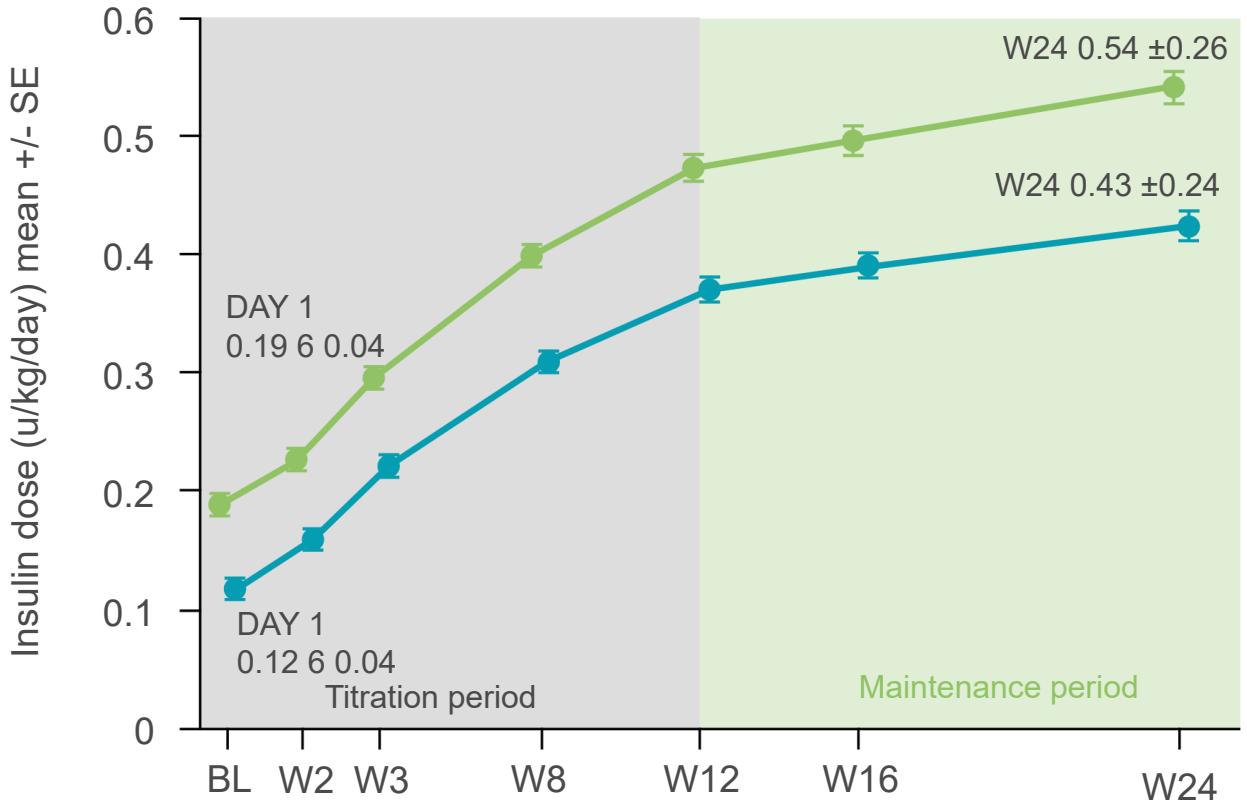
Rosenstock J, et al. Diabetes Care. 2018;41:2147–54.

Back to anytime hypoglycaemia rate

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)

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

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

Back to A1c reduction

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

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.

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

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

Prescribing Information: Toujeo® (insulin glargine 300 units/ml) Please refer to Summary of Product Characteristics (SmPC) before prescribing. Presentation: Toujeo SoloStar and DoubleStar 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. 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. The dose regimen (dose and timing) should be adjusted according to individual response. 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:** 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. The safety and efficacy of Toujeo in children and adolescents below 6 years of age have not been established. **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 prefilled pen, A new sterile needle must be attached before each injection. Needles must not be re-used. *Pregnancy and lactation:* There are 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. Prescribers should consult the SmPC in relation to other adverse reactions. **Legal Category:** POM. **Marketing Authorisation Number:** SoloStar 5 pen pack: EU/1/00/133/035; DoubleStar 5 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, 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact IEmedinfo@sanofi.com. **Date of preparation:** July 2022.

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Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie; email: medsafety@hpra.ie
Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com

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.

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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

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

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

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

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Legal category: POM.
Marketing Authorisation Holder: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany.
Marketing Authorisation Number(s): Cartridge: EU/1/00/134/006; SoloStar: EU/1/00/134/033.
For more information please contact: Sanofi, 18 Riverwalk, Citywest Business Campus, Dublin 24. IEmedinfo@sanofi.com.
Date of preparation: September 2024

Adverse events should be reported. Reporting forms and information can be found at: www.hpra.ie; Email: medsafety@hpra.ie. Suspected adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com.