Paediatric indication from ≥6 years

Toujeo®
insulin glargine 300 units/mL

Edition junior

The only paediatric trial comparing a second-generation insulin – Toujeo® vs Lantus® (insulin glargine 100 units/mL) – a standard of care in T1DM patients[1]

A 6-month, randomised, open-label, double-arm, parallel-group, non-inferiority study in 463 paediatric patients with T1DM (EDITION JUNIOR).[1]

Toujeo® is indicated for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.[2]

sanofi

T1DM, type 1 diabetes mellitus.

Danne T, *et al. Diabetes Care.* 2020; DOI:10.2337/dc19-1926. [Epub ahead of print].

This study was funded by Sanofi UK. Please refer to the Toujeo® Summary of Product Characteristics before prescribing. Prescribing information and Adverse event reporting can be found on the back cover of this item.

November 2024 | MAT-GB-2103599 (v3.0)

Paediatric population with T1DM[1]

A vulnerable population

Maintaining tight glycaemic control in T1DM patients is important as it can slow the progression of microvascular and macrovascular complications. However, many children with T1DM still experience frequent glycaemic fluctuations:[1,3]

~20% **of children in the UK achieve current HbA_{1c} target levels, despite intensive diabetes treatment[3]**

In children and adolescents with T1DM, hyperglycaemia and severe hypoglycaemia may be associated with:[1]

Changes in brain white and grey matter

Convulsions and loss of consciousness

10% **of children with T1DM in the UK experience severe hypoglycaemia in a 3-month period[4]**

Hyperglycaemia can also lead to diabetic ketoacidosis, which at its most serious may cause:[5]

Cerebral oedema

Acute respiratory distress

To reduce such complications, optimal insulin therapy options for children and adolescents with T1DM should provide effective glycaemic control while minimising the risk of hypoglycaemia and hyperglycaemia.[1]

The only paediatric trial comparing a second-generation insulin – Toujeo® vs Lantus® – a standard of care in T1DM patients[1,6–8]

Comparable and effective HbA_{1c} reduction at 26 weeks[1]

- HbA_{1c} LSM difference between groups at Week 26: Toujeo® (n=233), -0.4%; Lantus® (n=230), -0.4%. (95% CI): 0.004 (-0.17–0.18)

Edition junior

Comparable overall hypoglycaemia incidence[2]

- Incidence of hypoglycaemia in patients in any category was similar for both Toujeo® (97.9%) and Lantus® (98.%)

Numerically lower incidence and event rates of anytime (24 h) severe hypoglycaemia with Toujeo®*[1,6,7]

- Incidence of anytime severe hypoglycaemia at Week 26: Toujeo® (n=233), 6.0%; Lantus® (n=228), 8.8%. RR (95% CI): 0.68 (0.35–1.30)

Lower incidence of hyperglycaemia with ketosis† with Toujeo® at 26 weeks‡[1,7,8]

- Incidence of any hyperglycaemia with ketosis: Toujeo® (n=233), 6.4%; Lantus® (n=228), 11.8%. RR (95% CI): 0.54 (0.30–0.99) (*post-hoc* statistical analysis)

CI, confidence interval; **HbA_{1c}**, glycated haemoglobin; **LSM**, least squares mean; **RR**, relative risk; **SMPG**, self-monitored plasma glucose; **UK**, United Kingdom.

*Severe hypoglycaemia is defined as a child/adolescent with altered mental status and inability to self-care, is semiconscious or unconscious, or in coma with or without convulsions, who may require parenteral therapy (glucagon or glucose).

†Hyperglycaemia with ketosis events (SMPG) ≥252 mg/dL and ketone ≥1.5 mmol/L.

‡Numerically lower rate of hyperglycaemia with ketosis with Toujeo® vs Lantus® at 26 weeks: 0.30 vs 0.41 rate per patient-year, RR (95% CI): 0.56 (0.26–1.21). >50% of events were seen in just two patients.

The only paediatric trial comparing a second-generation insulin – Toujeo® vs Lantus® – a standard of care in T1DM patients[1]

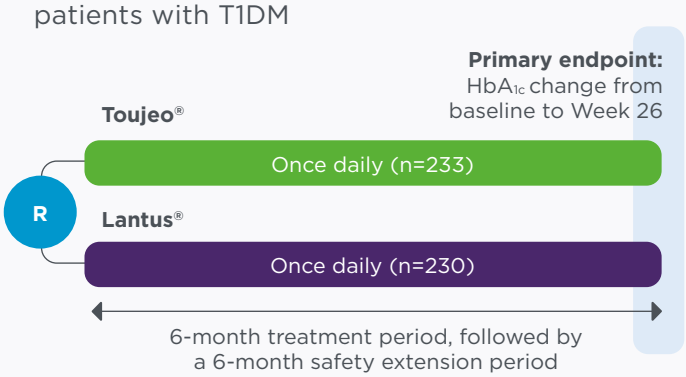
Study design and main endpoints[1,5,6]

Objective:[1]

- To demonstrate the non-inferiority of Toujeo® vs Lantus® in change in HbA_{1c} from baseline to Week 26 in children and adolescents with T1DM

Study design:[1]

- 6-month, randomised, open-label, double-arm, parallel-group, non-inferiority study in 463 patients with T1DM



Adapted from Danne T, *et al. Diabetes Care.* 2020.

Primary endpoint:[1]

- Change in HbA_{1c} levels from baseline to Week 26

Secondary endpoints:[1]

- Percentage of participants reaching target HbA_{1c} (<7.5% [58 mmol/mol]) or FPG levels (≤130 mg/dL) at Month 6, without any episode of severe and/or documented hypoglycaemia (<54 mg/dL) during last 3 months of main treatment period
- Change in FPG from baseline to Week 26

Safety endpoints:[1]

- Hypoglycaemia events
- Hyperglycaemia events with ketosis (SMPG, ≥252 mg/dL and ketone ≥1.5 mmol/L)
- Treatment-emergent adverse events (TEAEs)

Inclusion criteria:[1]

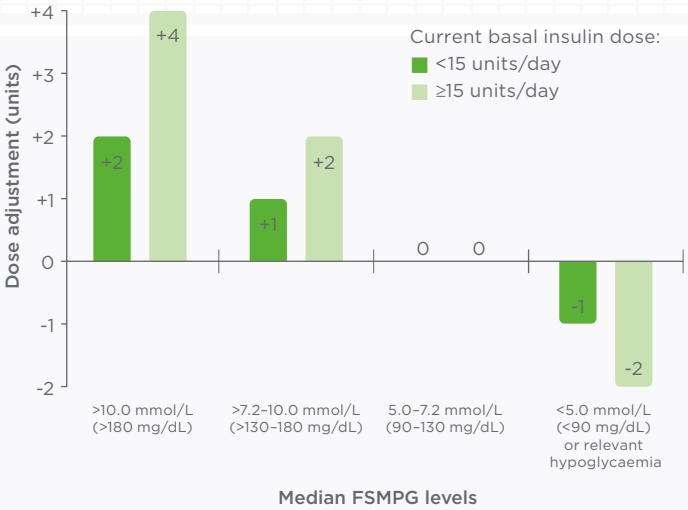
- 6–17 years
- T1DM duration ≥1 year
- Previous basal insulin plus fast-acting insulin therapy
- HbA_{1c} ≥7.5% and ≤11.0%
- No premix insulins in ≤3 months prior to screening

Study titration algorithm:[1]

Starting dose equal to the median total daily basal insulin dose from the 3 days prior to baseline visit.

- For participants previously taking >1 daily basal insulin dose, the starting basal insulin dose was reduced by 20% (with dose adjustments made weekly)

Toujeo® or Lantus® titrated to FSMPG target of 5.0–7.2 mmol/L (90–130 mg/dL) while avoiding hypoglycaemia*[5,6]



Adapted from Danne T, *et al.* 2020. Supplementary Data and Danne T, *et al.* 2020. ATTD.

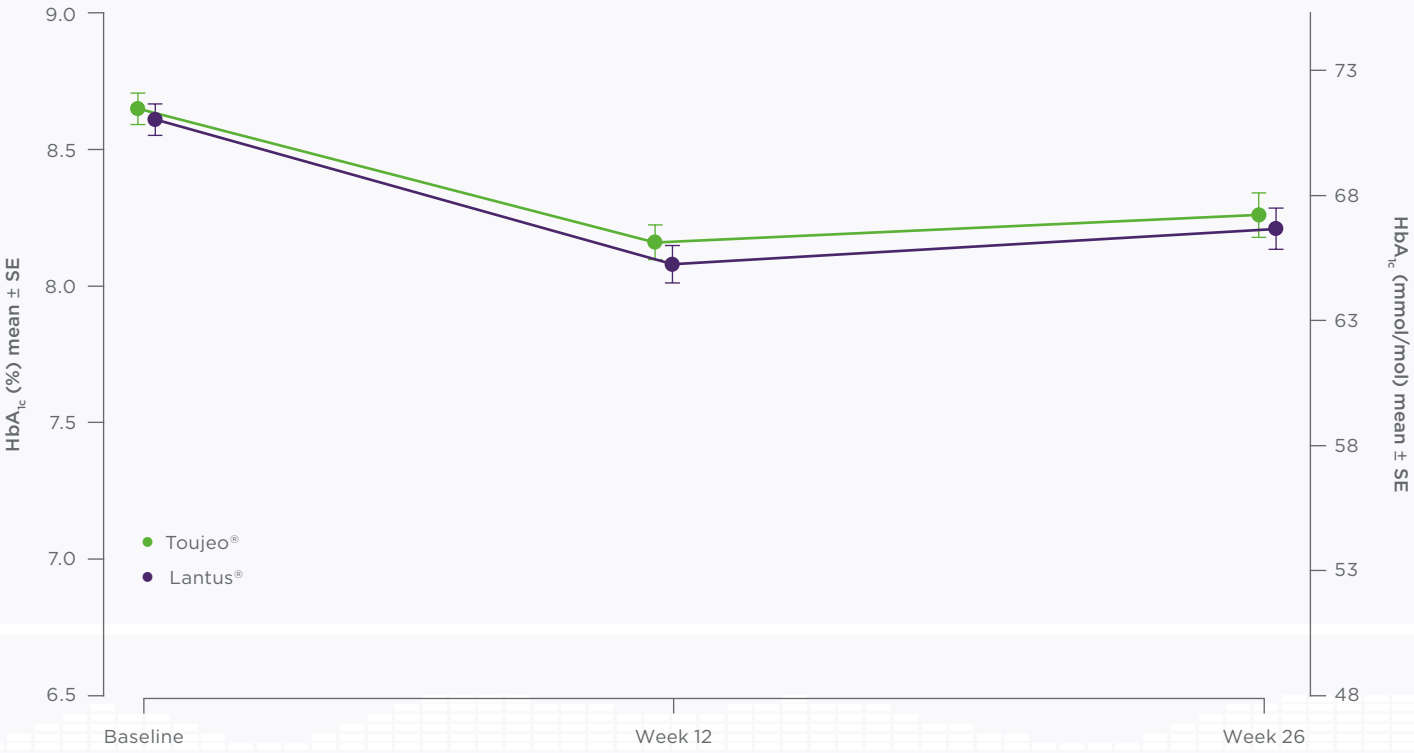
FPG, fasting plasma glucose; **FSMPG**, fasting self-monitored plasma glucose; **R**, randomisation; **TEAE**, treatment emergent adverse event.

*Doses may be reduced at any time in case of hypoglycaemia, in case of severe hypoglycaemia, in addition to dose reduction, upward titration may be stopped for 1-week.

Comparable and effective HbA_{1c} reduction at 26 weeks with Toujeo® vs Lantus®[1]

Primary endpoint: Change in HbA_{1c} levels over the 26-week treatment period[1]

Mean (SE) HbA_{1c} by visit[1]



Adapted from Danne T, *et al. Diabetes Care.* 2020.

Toujeo® and Lantus® conferred similar HbA_{1c} reductions at Week 26 from baseline, confirming non-inferiority of Toujeo® vs Lantus® at the 0.3% margin.[1]

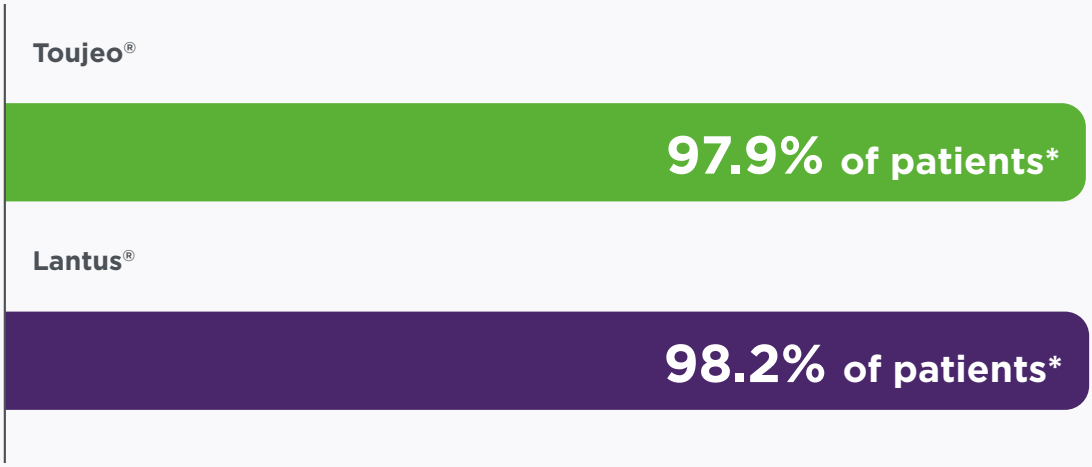
Lantus® and Toujeo® are not bioequivalent and are not directly interchangeable.[2]

SE, standard error.

Comparable overall hypoglycaemia with Toujeo® vs Lantus®[2,7]

Overall hypoglycaemia incidence[2]

Incidence of hypoglycaemia in patients in any category[2]



Adapted from Toujeo® SmPC.

Similar incidence of anytime (24 h) and nocturnal (00:00–05:59 h) hypoglycaemia with Toujeo® vs Lantus®†[7]

	Number of participants (%)		
Hypoglycaemia category	**Toujeo® n=233**	**Lantus® n=228**	**Relative risk (95% CI)**
Anytime hypoglycaemia (24 h) Severe and/or documented			
≤70 mg/dL (≤3.9 mmol/L)	226 (97.0)	223 (97.8)	0.99 (0.96–1.02)
<54 mg/dL (<3.0 mmol/L)	187 (80.3)	191 (83.8)	0.96 (0.88–1.04)
Nocturnal hypoglycaemia (00:00–05:59 h) Severe and/or documented			
≤70 mg/dL (≤3.9 mmol/L)	163 (70.0)	160 (70.2)	1.00 (0.88–1.12)
<54 mg/dL (<3.0 mmol/L)	63 (27.0)	57 (25.0)	1.09 (0.80–1.47)

Adapted from Danne T, *et al.* 2020. ATTD.

ADA, American Diabetes Association; **ISPAD**, International Society of Paediatric and Adolescent Diabetes.

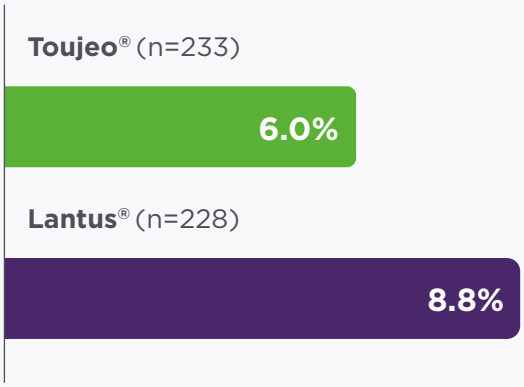
Safety population (Toujeo®, n=233; Lantus®, n=228). Corresponding event rates were comparable across both groups. Randomisation was stratified at screening by HbA_{1c} (<8.5% and ≥8.5%) and by age (<12 years and ≥12 years), configured to ensure that ≥30% of participants would be <12 years of age. Percentage of patients with at least one event of hypoglycaemia according to different ADA and ISPAD-defined categories are shown.

*Reporting at least one event.

†Severe hypoglycaemia is defined as a child/adolescent with altered mental status and inability to self-care, is semiconscious or unconscious, or in coma with or without convulsions, who may require parenteral therapy (glucagon or glucose).

Numerically lower incidence and event rate of severe hypoglycaemia* with Toujeo® vs Lantus®[1,6,7]

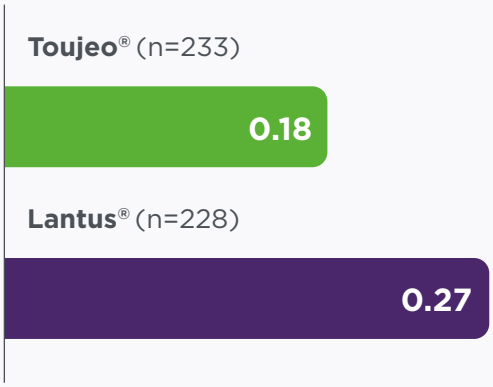
Incidence of severe hypoglycaemia (24 h) (%)* with Toujeo® vs Lantus® at Week 26[1,6,7]



RR (95% CI): 0.68 (0.35–1.30)
Numerically lower[1]

Adapted from Danne T, *et al. Diabetes Care.* 2020.

Event rate of severe hypoglycaemia (24 h)* (event per participant-year) with Toujeo® vs Lantus®[1,6,7]

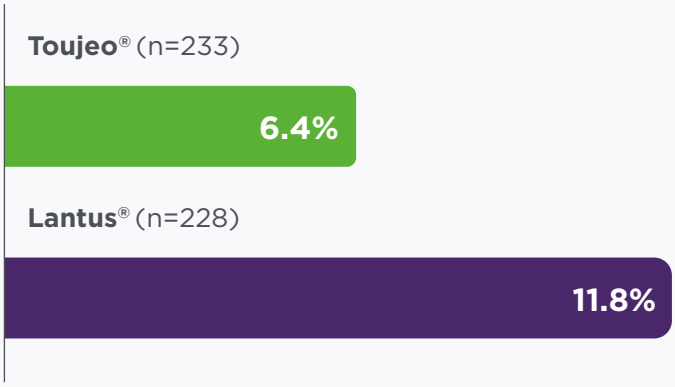


RR (95% CI): 0.69 (0.32–1.50)
Numerically lower[1]

Adapted from Danne T, *et al. Diabetes Care.* 2020.

Hyperglycaemia with ketosis with Toujeo® vs Lantus® at 26 weeks†[1,7,8]

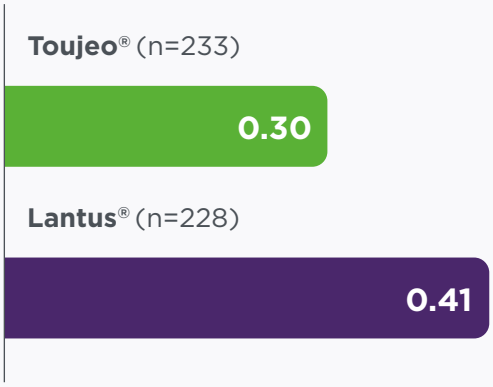
Lower incidence of hyperglycaemia (%) with ketosis with Toujeo® vs Lantus® at 26 weeks[1,7]



RR (95% CI): 0.54 (0.30–0.99)[7]
***Post-hoc* statistical analysis**
(not adjusted for multiplicity)[1]

Adapted from Danne T, *et al. Diabetes Care.* 2020.

Numerically lower event rate of hyperglycaemia with ketosis† at Week 26 with Toujeo® vs Lantus®[1,8]



RR (95% CI): 0.56 (0.26–1.21). Numerically lower[1,8]
>50% of all documented ketone values ≥1.5 mmol/L were reported by two patients[1]

Adapted from Danne T, *et al. Diabetes Care.* 2020.

Safety population (Toujeo®, n=233; Lantus®, n=228).

*Severe hypoglycaemia is defined as a child/adolescent with altered mental status and inability to self-care, is semiconscious or unconscious, or in coma with or without convulsions, who may require parenteral therapy (glucagon or glucose).

†Hyperglycaemia with ketosis events (SMPG) ≥252 mg/dL and ketone ≥1.5 mmol/L.

Similar adverse event profile with Toujeo® vs Lantus®[1]

TEAE during the 26-week treatment period (safety population)*[1]

Participants with at least one TEAE, n (%)	Toujeo® n=233	Lantus® n=228
TEAE	152 (65.2)	150 (65.8)
Treatment-emergent SAE	17 (7.3)	21 (9.2)
TEAE leading to permanent treatment discontinuation	2 (0.9)	2 (0.9)
TEAE leading to death	1 (0.4)	0

Adapted from Danne T, *et al. Diabetes Care.* 2020.

No new safety issues were identified with respect to adverse events and standard safety parameters. One fatality occurred during the study in the Toujeo® group and the event was not considered related to the study treatment.[1]

Conclusions[1,6–8]

EDITION JUNIOR is the only paediatric trial that compared a second-generation insulin – Toujeo® vs Lantus® – a standard of care in T1DM patients, with key findings showing:

- Comparable and effective HbA_{1c} reduction from baseline to 26 weeks[1]
- Comparable incidence of overall hypoglycaemia[1,7]
- Numerically lower incidence and event rates of anytime (24 h) severe hypoglycaemia with Toujeo®[1,6,7]
  - Incidence of anytime severe hypoglycaemia at Week 26: Toujeo®, 6.0%; Lantus®, 8.8%; RR (95% CI): 0.68 (0.35–1.30)[1,6,7]
- Lower incidence and event rate of hyperglycaemia with ketosis at 26 weeks with Toujeo®[1,7,8]
  - Incidence of participants with ≥1 TEAE of hyperglycaemia with ketosis: Toujeo®, 6.4%; Lantus®, 11.8%; RR (95% CI): 0.54 (0.30–0.99) (*post-hoc* analysis)[1,7]

SAE, severe adverse event.

*Safety population (Toujeo®, n=233; Lantus®, n=288).

References: 1. Danne T, et al. Diabetes Care. 2020. DOI:10.2337/dc19-1926. [Epub ahead of print]. 2. Toujeo® Summary of Product Characteristics. 3. Watts W, et al. Diabetes Care for Children & Young People. 2014.3(3):89–95. 4. Wright NP, et al. Arch Dis Child. 2003;88:155–156. 5. Agiostratidou G, et al. Diabetes Care. 2017;40:1622–1630. 6. Danne T, et al. Diabetes Care. 2020. DOI:10.2337/dc19-1926. [Epub ahead of print]. Supplementary Data. 7. Danne T, et al. Insulin glargine 300 U/mL (Gla-300) provides effective glycaemic control in youths with type 1 diabetes (T1D): the EDITION JUNIOR study [PowerPoint presentation] presented at International Conference on Advanced Technologies & Treatments for Diabetes 2020; February 19–22: Madrid, Spain. S04. 8. Sanofi Data on File. SAGB.TJO.20.03.0549.

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

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) (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: 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.

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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

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November 2024 | MAT-GB-2103599 (v3.0)