CONTINUOUS GLUCOSE MONITORING PROFILES CAN HELP IDENTIFY CLINICAL CHALLENGES IN REAL LIFE

Toujeo® insulin glargine 300U/mL

NOCTURNAL HYPOGLYCAEMIA AND THE SOMOGYI PHENOMENON

Case details provided by Diabetes Specialist
Dr Fernando Gomez-Peralta, MD PhD

Clinical profile

Patient	Age	Condition	Duration
Male	42 years	Type 1	17 years

Other medical history

Dyslipidaemia, treated with simvastatin 20 mg once daily

Current diabetes medication

Lantus (insulin glargine 100 units/mL) (34 units each day before dinner)

Apidra (insulin glulisine 100 units/mL) (10, 14 and 18 units with breakfast, lunch, and dinner, respectively, with daily adjustments dependant on meals and glycaemia)

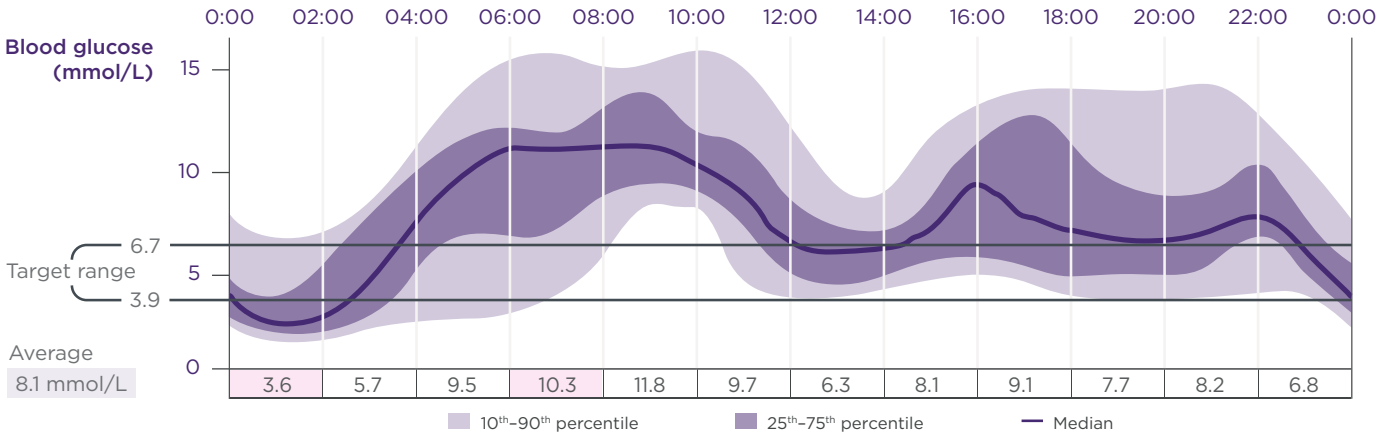
Toujeo® is indicated for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

Prescribing information is available at the end of this document.

Clinical challenge

Nocturnal hypoglycaemia (midnight to 3AM) causing morning fasting hyperglycaemia (the Somogyi phenomenon)

Ambulatory glucose profile—before



Why choose Toujeo®?

Key findings from a post-hoc meta-analysis of three 6-month, Phase III clinical trials* that compared Toujeo vs Lantus (insulin glargine 100 units/mL) demonstrated:

- **Comparable and effective HbA_{1c} reduction at 6 months with Toujeo and Lantus (insulin glargine 100 units/mL)[1]**
  - HbA_{1c} LSM difference in the T1DM study pool from baseline to 6 months: Toujeo (n=628), −0.38%; Lantus (insulin glargine 100 units/mL) (n=624), −0.44%. RR (95% CI): 0.05 (−0.04 to 0.15)
- **Risk of severe hypoglycaemia: lower risk of severe hypoglycaemia† with Toujeo vs Lantus (insulin glargine 100 units/mL) in a broad population with T1DM in the full study period[1]**
  - Incidence of severe hypoglycaemia† from baseline to 6 months in the T1DM study pool: Toujeo (n=629), 6.2%; Lantus (insulin glargine 100 units/mL) (n=624), 9.3%. OR (95% CI): 0.65 (0.42 to 0.98)

Activity profile: Toujeo has a stable activity profile beyond 24 hours with a flexible 6-hours dosing window when needed (+/- 3 hours)[2]

*The following T1DM patient populations were pooled in this meta-analysis: EDITION 4 (n=549): adult patients (age ≥18 years); EDITION JP 1 (n=243): adult patients (age ≥18 years); EDITION JUNIOR (n=463): children and adolescents (age 6–17 years).
†Severe hypoglycaemia was defined as a) in adults as hypoglycaemic event that required assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions, or b) in children and adolescents as having altered mental status and inability to assist in their care, being semiconscious or unconscious, or in coma ± convulsions that may require parenteral therapy (glucagon and/or glucose).

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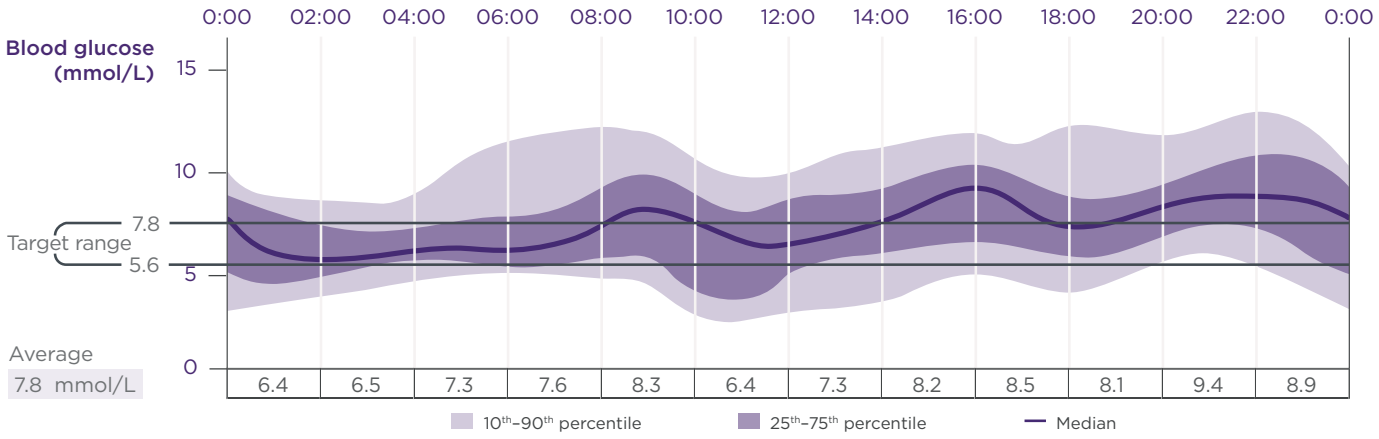
Treatment solution

Switch to second-generation basal insulin Toujeo (insulin glargine 300 units/mL; 37 units each day before dinner) and continue Apidra (insulin glulisine 100 units/mL) (10, 14 and 18 units with breakfast, lunch, and dinner, respectively)

Toujeo® insulin glargine 300U/mL

Ambulatory glucose profile—after 2 weeks of Toujeo



Outcomes

1 After 2 weeks of Toujeo, the patient experienced a reduction in nocturnal hypoglycaemia

2 The morning fasting hyperglycaemia (Somogyi phenomenon) resolved

3 Due to less nocturnal hypoglycaemia, the median blood glucose was within the target range (5.6–7.8 mmol/L) in the morning period (midnight to 8AM)

4 Emerging evidence suggests that improved blood glucose profile is important for the long-term care of people with type 1 diabetes[3]

When switching from Lantus (insulin glargine 100 units/mL) to Toujeo, this can initally be done on a unit-to-unit basis, but further titration may be required. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter.[2]

CI, confidence interval; HbA_{1c}, glycated haemoglobin; LSM, least squares mean; OR, odds ratio; RR, relative risk; T1DM, type 1 diabetes mellitus.

1. Danne T, et al. Diabetes Obes Metab 2020; 22:1880-1885. 2. Toujeo Summary of Product Characteristics. 3. Zhou Z, et al. Cardiovasc Diabetol. 2020;19:102.

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: Toujeo® (insulin glargine 300 units/ml) (IE)

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 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 (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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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 (IE)
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.
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.

Prescribing Information: Apidra® (insulin glulisine 100 units/ml) (GB)

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

Presentation: Apidra 100 Units/ml solution for injection in a vial each containing 10ml of solution. Apidra 100 Units/ml solution for injection in a cartridge, or in a pre-filled pen, each containing 3ml of solution. Each ml contains 100 Units insulin glulisine (equivalent to 3.49mg).
Indication: Treatment of adults, adolescents and children 6 years or older, with diabetes mellitus, where treatment with insulin is required.
Dosage and Administration: Apidra should be used in regimens that include an intermediate or long acting insulin or basal insulin analogue and can be used with oral hypoglycaemic agents. The dose of Apidra should be individually adjusted. Apidra must not be mixed with other medicinal products except NPH human insulin. **Method of administration:** Subcutaneous use: Apidra cartridges and SoloStar are only suitable for subcutaneous injections from a reusable pen and prefilled pen, respectively. Apidra should be given by subcutaneous injection (into the abdominal wall, thigh or deltoid) shortly (0-15 min) before or soon after meals or by continuous subcutaneous pump infusion (into the abdominal wall). The rate of absorption, and consequently the onset and duration of action, may be affected by the injection site, exercise and other variables. Subcutaneous injection in the abdominal wall ensures a slightly faster absorption than other injection sites. Care should be taken to ensure that a blood vessel has not been entered. After injection, the site of injection should not be massaged. Injection sites and infusion sites within an injection area should be rotated from one injection to the next (see precautions and warnings). Patients must be educated to use proper injection techniques. Intravenous use (vial only): Apidra must not be mixed with glucose, Ringer's solution or with any other insulin and must be administered by a healthcare professional. Continuous Subcutaneous Insulin Infusion (CSII) (vial only): Apidra can be used for CSII in pump systems suitable for insulin infusion with the appropriate catheters and reservoirs. When used with a subcutaneous insulin infusion pump, Apidra must not be mixed with diluents or any other insulin. The infusion set and reservoir used with Apidra must be changed at least every 48 hours using aseptic technique. These instructions may differ from general pump manual instructions. It is important that patients follow the Apidra specific instructions, be comprehensively instructed on the use of the CSII pump system and must have an alternative insulin delivery system available in case of pump system failure, in order to prevent serious adverse events.
Special Populations: Elderly patients, renal and hepatic impairment: Deterioration or decrease of renal or hepatic function may lead to a decrease in insulin requirements. Paediatric population: There is insufficient clinical information on the use of Apidra in children younger than the age of 6 years.
Contraindications: Hypoglycaemia. Hypersensitivity to insulin glulisine 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. 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. Transfer to another type/brand of insulin: This should be done under strict medical supervision and may result in the need for a change in dose. Concomitant oral antidiabetic treatment may need to be adjusted. Medication errors: Insulin label must always be checked before each injection to avoid medication errors between Apidra and other insulins. Hyperglycaemia: The use of inadequate doses or discontinuation of treatment, especially in insulin-dependent diabetic, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal. Hypoglycaemia: The time of occurrence of hypoglycaemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen is changed. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma, or death. Insulin requirements may be altered during illness or emotional disturbances. Apidra Vial: Malfunction of the insulin pump, infusion set or handling errors can rapidly lead to hyperglycaemia, ketosis and diabetic ketoacidosis. Interim subcutaneous injections with Apidra may be required. Excipients: This medicine is essentially 'sodium free'. Apidra also contains metacresol, which may cause allergic reactions.
Interactions: Cases of cardiac failure have been reported when Pioglitazone is used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. A number of substances affect glucose metabolism and may require dose adjustment of Apidra. Please see SmPC for full details. **Pregnancy and breast-feeding:** Caution should be exercised when prescribing to pregnant women. Careful monitoring of glucose control is essential. It is unknown whether Apidra is excreted in human milk, but in general insulin does not pass into breast milk and is not absorbed after oral administration. Breast-feeding mothers may require adjustments in insulin dose and diet.
Adverse Reactions: Very common: Hypoglycaemia. Potentially becoming severe and may lead to unconscious and/or convulsions and temporary or permanent impairment of brain function or even death. Common: Injection site reactions and local hypersensitivity reactions, which are usually transitory and normally disappear during continued treatment. Uncommon: Systemic hypersensitivity reactions. Rare: Lipodystrophy. Frequency not known: Cutaneous amyloidosis, hyperglycaemia (potentially leading to Diabetic ketoacidosis). *Prescribers should consult the SmPC in relation to other adverse reactions.*
GB List Price and Marketing Authorisation Number: Apidra 1 x 10ml vial (PLGB 04425/0798): £16.00; Apidra 5 x 3ml cartridge (PLGB 04425/0799): £28.30; Apidra 5 x 3ml SoloStar pre-filled pens (PLGB 04425/0800): £28.30.
Legal Category: POM
Marketing Authorisation Holder: Sanofi, 410 Thames Valley Drive, Reading, Berkshire, RG6 1PT, UK
Further information is available from: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.
Date of preparation: September 2022

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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: Apidra® (insulin glulisine 100 units/ml) (NI)

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

Presentation: Apidra 100 Units/ml solution for injection in a vial each containing 10ml of solution. Apidra 100 Units/ml solution for injection in a cartridge, or in a pre-filled pen, each containing 3ml of solution. Each ml contains 100 Units insulin glulisine (equivalent to 3.49mg).
Indication: Treatment of adults, adolescents and children 6 years or older, with diabetes mellitus, where treatment with insulin is required.
Dosage and Administration: Apidra should be used in regimens that include an intermediate or long acting insulin or basal insulin analogue and can be used with oral hypoglycaemic agents. The dose of Apidra should be individually adjusted. Apidra must not be mixed with other medicinal products except NPH human insulin. **Method of administration:** Subcutaneous use: Apidra cartridges and SoloStar are only suitable for subcutaneous injections from a reusable pen and prefilled pen, respectively. Apidra should be given by subcutaneous injection (into the abdominal wall, thigh or deltoid) shortly (0-15 min) before or soon after meals or by continuous subcutaneous pump infusion (into the abdominal wall). The rate of absorption, and consequently the onset and duration of action, may be affected by the injection site, exercise and other variables. Subcutaneous injection in the abdominal wall ensures a slightly faster absorption than other injection sites. Care should be taken to ensure that a blood vessel has not been entered. After injection, the site of injection should not be massaged. Injection sites and infusion sites within an injection area should be rotated from one injection to the next (see precautions and warnings). Patients must be educated to use proper injection techniques. Intravenous use (vial only): Apidra must not be mixed with glucose, Ringer's solution or with any other insulin and must be administered by a healthcare professional. Continuous Subcutaneous Insulin Infusion (CSII) (vial only): Apidra can be used for CSII in pump systems suitable for insulin infusion with the appropriate catheters and reservoirs. When used with a subcutaneous insulin infusion pump, Apidra must not be mixed with diluents or any other insulin. The infusion set and reservoir used with Apidra must be changed at least every 48 hours using aseptic technique. These instructions may differ from general pump manual instructions. It is important that patients follow the Apidra specific instructions, be comprehensively instructed on the use of the CSII pump system and must have an alternative insulin delivery system available in case of pump system failure, in order to prevent serious adverse events.
Special Populations: Elderly patients, renal and hepatic impairment: Deterioration or decrease of renal or hepatic function may lead to a decrease in insulin requirements. Paediatric population: There is insufficient clinical information on the use of Apidra in children younger than the age of 6 years.
Contraindications: Hypoglycaemia. Hypersensitivity to insulin glulisine 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. 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. Transfer to another type/brand of insulin: This should be done under strict medical supervision and may result in the need for a change in dose. Concomitant oral antidiabetic treatment may need to be adjusted. Medication errors: Insulin label must always be checked before each injection to avoid medication errors between Apidra and other insulins. Hyperglycaemia: The use of inadequate doses or discontinuation of treatment, especially in insulin-dependent diabetic, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal. Hypoglycaemia: The time of occurrence of hypoglycaemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen is changed. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma, or death. Insulin requirements may be altered during illness or emotional disturbances. Apidra Vial: Malfunction of the insulin pump, infusion set or handling errors can rapidly lead to hyperglycaemia, ketosis and diabetic ketoacidosis. Interim subcutaneous injections with Apidra may be required. Excipients: This medicine is essentially 'sodium free'. Apidra also contains metacresol, which may cause allergic reactions.
Interactions: Cases of cardiac failure have been reported when Pioglitazone is used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. A number of substances affect glucose metabolism and may require dose adjustment of Apidra. Please see SmPC for full details. **Pregnancy and breast-feeding:** Caution should be exercised when prescribing to pregnant women. Careful monitoring of glucose control is essential. It is unknown whether Apidra is excreted in human milk, but in general insulin does not pass into breast milk and is not absorbed after oral administration. Breast-feeding mothers may require adjustments in insulin dose and diet.
Adverse Reactions: Very common: Hypoglycaemia. Potentially becoming severe and may lead to unconscious and/or convulsions and temporary or permanent impairment of brain function or even death. Common: Injection site reactions and local hypersensitivity reactions, which are usually transitory and normally disappear during continued treatment. Uncommon: Systemic hypersensitivity reactions. Rare: Lipodystrophy. Frequency not known: Cutaneous amyloidosis, hyperglycaemia (potentially leading to Diabetic ketoacidosis). *Prescribers should consult the SmPC in relation to other adverse reactions.*
Legal Category: POM
Marketing Authorisation Holder: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany.
Marketing Authorisation Number: Apidra 1 x 10ml vial: EU/1/04/285/001; Apidra 5 x 3ml cartridge: EU/1/04/285/008; Apidra 5 x 3ml SoloStar pre-filled pens: EU/1/04/285/032.
Further information is available from: Medical Information, Sanofi, 18 Riverwalk, Citywest Business Campus, Dublin 24. IEmedinfo@sanofi.com.
Date of preparation: September 2022

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Prescribing Information: Apidra® (insulin glulisine 100 units/ml) (IE)

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

Presentation: Apidra 100 Units/ml solution for injection in a vial each containing 10ml of solution. Apidra 100 Units/ml solution for injection in a cartridge, or in a pre-filled pen, each containing 3ml of solution. Each ml contains 100 Units insulin glulisine (equivalent to 3.49mg).
Indication: Treatment of adults, adolescents and children 6 years or older, with diabetes mellitus, where treatment with insulin is required.
Dosage and Administration: Apidra should be used in regimens that include an intermediate or long acting insulin or basal insulin analogue and can be used with oral hypoglycaemic agents. The dose of Apidra should be individually adjusted. Apidra must not be mixed with other medicinal products except NPH human insulin. **Method of administration:** Subcutaneous use: Apidra cartridges and SoloStar are only suitable for subcutaneous injections from a reusable pen and prefilled pen, respectively. Apidra should be given by subcutaneous injection (into the abdominal wall, thigh or deltoid) shortly (0-15 min) before or soon after meals or by continuous subcutaneous pump infusion (into the abdominal wall). The rate of absorption, and consequently the onset and duration of action, may be affected by the injection site, exercise and other variables. Subcutaneous injection in the abdominal wall ensures a slightly faster absorption than other injection sites. Care should be taken to ensure that a blood vessel has not been entered. After injection, the site of injection should not be massaged. Injection sites and infusion sites within an injection area should be rotated from one injection to the next (see precautions and warnings). Patients must be educated to use proper injection techniques. Intravenous use (vial only): Apidra must not be mixed with glucose, Ringer's solution or with any other insulin and must be administered by a healthcare professional. Continuous Subcutaneous Insulin Infusion (CSII) (vial only): Apidra can be used for CSII in pump systems suitable for insulin infusion with the appropriate catheters and reservoirs. When used with a subcutaneous insulin infusion pump, Apidra must not be mixed with diluents or any other insulin. The infusion set and reservoir used with Apidra must be changed at least every 48 hours using aseptic technique. These instructions may differ from general pump manual instructions. It is important that patients follow the Apidra specific instructions, be comprehensively instructed on the use of the CSII pump system and must have an alternative insulin delivery system available in case of pump system failure, in order to prevent serious adverse events.
Special Populations: Elderly patients, renal and hepatic impairment: Deterioration or decrease of renal or hepatic function may lead to a decrease in insulin requirements. Paediatric population: There is insufficient clinical information on the use of Apidra in children younger than the age of 6 years.
Contraindications: Hypoglycaemia. Hypersensitivity to insulin glulisine 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. 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. Transfer to another type/brand of insulin: This should be done under strict medical supervision and may result in the need for a change in dose. Concomitant oral antidiabetic treatment may need to be adjusted. Medication errors: Insulin label must always be checked before each injection to avoid medication errors between Apidra and other insulins. Hyperglycaemia: The use of inadequate doses or discontinuation of treatment, especially in insulin-dependent diabetic, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal. Hypoglycaemia: The time of occurrence of hypoglycaemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen is changed. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma, or death. Insulin requirements may be altered during illness or emotional disturbances. Apidra Vial: Malfunction of the insulin pump, infusion set or handling errors can rapidly lead to hyperglycaemia, ketosis and diabetic ketoacidosis. Interim subcutaneous injections with Apidra may be required. Excipients: This medicine is essentially 'sodium free'. Apidra also contains metacresol, which may cause allergic reactions.
Interactions: Cases of cardiac failure have been reported when Pioglitazone is used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. A number of substances affect glucose metabolism and may require dose adjustment of Apidra. Please see SmPC for full details. **Pregnancy and breast-feeding:** Caution should be exercised when prescribing to pregnant women. Careful monitoring of glucose control is essential. It is unknown whether Apidra is excreted in human milk, but in general insulin does not pass into breast milk and is not absorbed after oral administration. Breast-feeding mothers may require adjustments in insulin dose and diet.
Adverse Reactions: Very common: Hypoglycaemia. Potentially becoming severe and may lead to unconscious and/or convulsions and temporary or permanent impairment of brain function or even death. Common: Injection site reactions and local hypersensitivity reactions, which are usually transitory and normally disappear during continued treatment. Uncommon: Systemic hypersensitivity reactions. Rare: Lipodystrophy. Frequency not known: Cutaneous amyloidosis, hyperglycaemia (potentially leading to Diabetic ketoacidosis). *Prescribers should consult the SmPC in relation to other adverse reactions.*
NI List Price and Marketing Authorisation Number: Apidra 1 x 10ml vial (EU/1/04/285/001): £16.00; Apidra 5 x 3ml cartridge (EU/1/04/285/008): £28.30; Apidra 5 x 3ml SoloStar pre-filled pens (EU/1/04/285/032): £28.30.
Legal Category: POM
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.
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