A guide to starting Toujeo (Insulin Glargine 300units/ml)

A promotional aid, provided by Sanofi, for UK Healthcare Professionals to support people transitioning to Toujeo Solostar (Insulin Glargine 300units/ml) from either a once daily or weekly GLP-1 Receptor Agonist (GLP-1 RA). Please use alongside the video case studies Dave and Grace. These resources have been developed by Anne Goodchild, Diabetes Specialist Nurse and Lead trainer for PITstop (Programme of injectable therapies) course. Please consult local guidelines and refer to the Summary of Product Characteristics before initiating any treatment.

INSULIN TREATMENT SHOULD ONLY BE INITIATED, TITRATED, AND MONITORED BY HEALTHCARE PROFESSIONALS WITH THE RELEVANT EXPERTISE AND TRAINING. IF YOU ARE SUPPORTING PATIENTS DURING THE SHORTAGE OF GLP-1 RECEPTOR AGONISTS, PLEASE WORK ALONGSIDE A SPECIALIST IN INSULIN INITIATION TO DISCUSS EACH CASE AND THE PLAN OF ACTION.

The advice in this material is in line with recommendations provided within the PITstop training programme.
Local guidelines may vary and should also be consulted

Resources

- Dummy SoloStar device to demonstrate an injection
- Toujeo SoloStar information booklet
- 4mm needles in line with local formulary
- Blood glucose monitors (ready to teach people on treatment regimens not involving Sulfonylureas)
- DVLA insulin leaflet INF294, DIAB1 form (complete online). For Group 2 drivers, insulin leaflet INS186, VDIAB1I form www.gov.uk/diabetes-driving
- PITstop patient handbook and HbA1c chart www.pitstopdiabetes.co.uk/resources
- Recommend resources on the NHS Better Health website and referral to the NHS digital weight management programme to coincide with the initial 3-months having started insulin
- Hypoglycaemia education resources for patients www.diabetes.org.uk/guide-to-diabetes/complications/hypos

Prescription

- Sharps bin, plus understanding of local collection policy
- 4mm needles (according to local formulary)
- Make any changes to the current treatment regimen (including the GLP-1 RA)
- Blood glucose strips (may require a monitor, plus education on how to use)
- Toujeo SoloStar x 3

Note: the Toujeo device in use, can be kept out of the fridge for a maximum of up to 6 weeks, below 30°c[1].

For record keeping the following templates are available:

- Ardens EMIS PITstop insulin template
- SystmOne Ardens Diabetes template (PITstop page)

Process

1. Assessment and initiation stage (requires a number of short appointments or a 30–60-minute appointment)	Tick
Find out about the individual's eating pattern, lifestyle and how they feel about the treatment regimen changes. You may agree to set a lifestyle goal (review after 3 months)[5].	
Provide written information about changes to current oral medication on the day insulin is started. Continue Metformin and SGLT-2 inhibitor, unless contra-indicated. Stop Sulfonylureas[3].	
Describe the time/action profile of Toujeo, as a once a day injection that lasts over 24 hours with a stable and prolonged duration of action[1,2]. This helps explain how the insulin works and fits in with their current lifestyle. Agree the time of the day to perform the injection and explain that if needed*, they can administer Toujeo up to 3 hours before or after their usual time of administration due to the duration of action[1], without effecting their glucose control or risk of hypoglycaemia. *Summary of Product Characteristics does state it's preferable to take it at the same time each day and to use the window only when needed **Work out the starting dose:** 0.2 units / kg of total body weight[3,8] **Examples:** prescribe Toujeo as a repeat variable 1. Dave's weight 136 kg 0.2 units / kg = 28 units daily. 2. Grace's weight 78.5 kg 0.2 units / kg = 16 units daily.	
Start insulin using the pictorial guide in the Toujeo SoloStar information booklet[6] (pages 8/9)	
Teach injection technique in line with Trend Diabetes' Injection Technique Matters[7].	
Reinforce the DVLA requirements when starting insulin, including informing the DVLA[4] (see resources).	
Reinforce understanding about what hypoglycaemia is, prevention and management (including when driving).	
Revisit blood glucose monitoring requirements for driving. If their current treatment regimen does not involve a Sulfonylurea, they will need to be given a monitor and strips in line with local formulary and taught self-monitoring. To enable insulin adjustments, testing their fasting blood glucose daily, is required. **Group 1** drivers must test within 2-hours of driving and every 2 hours during a long drive[4]. **Group 2** drivers must stop driving their Group 2 vehicle when starting insulin until the DVLA has made a licensing decision. Once working they must test twice daily on days off and within 2-hours of driving and every 2 hours during a shift[4].	
Agree a long-term target HbA1c. You may need to agree an interim target HbA1c for three months and a fasting blood glucose target range, in line with the target HbA1c. Examples below[5]:	

Target HbA1c (mmol/mol)	Target fasting blood glucose range (also the pre meal range) (mmol/l)
53	5.0 - 6.5
58	5.5 - 7.5
64	6.5 - 8.5
69	7.0 - 9.0
75	8.0 - 10.0
86	9.0 - 11.0

2. Review one week after starting insulin (phone or face-to-face)	Tick
Self-management of insulin injections and monitoring. How have they got on? Any issues or concerns?	
Review injection technique and reinforce site rotation.	
Have they informed the DVLA[4]?	
Have they understood hypoglycaemia key messages?	
Start teaching insulin adjustment using the last week's fasting blood glucose levels and the agreed fasting target range. Toujeo SoloStar information booklet[6] (pages 10-13). **Toujeo adjustment (simplified):** • look at the last 3 fasting results[3,5,6,8] • take the middle of the results and compare with the agreed fasting target range[6] • if above the target increase Toujeo by 2 units[5,6,8] • if below the target reduce Toujeo by 2 units[5,6,8] • if any blood glucose is below 4 mmol/mol, reduce Toujeo by 4 units[6]. Can they repeat this every 3 days until their appointment in 3 weeks (a potential 7 adjustment steps)? Do they require telephone support? Ideally phone on an adjustment day. Ask them what they plan to do, rather than adjust the insulin for them. **General rule: titrate Toujeo until either:** • they have reached their fasting target range (you may need to adjust the target if you started with a high interim target Hba1c) or • they have reached 0.5 units / kg total body weight as this is what is recommended as general insulin requirement for an individual[3]. Dave – stop and review at 68 units Grace – stop and review at 38 units	
Assess self-management ability re. insulin adjustment (consider phone support if required).	
Agree a review date in approximately 3 weeks.	
3. Review one month after starting insulin	**Tick**
Self-management of insulin injections and monitoring. How have they got on? Any issues or concerns?	
Ensure they have informed the DVLA[4].	
Progress with insulin adjustment. Note current dose in their records.	
If within target blood glucose range, consider adjusting the target range (never lower than 5 – 6.5mmol/l) and continue adjustments to the new target range.	
Any adjustment to the insulin dose required today?	
Assess self-management ability re. insulin adjustment (consider phone support if required).	
Discuss illness management with insulin and review learning[5].	
Dicuss activity management with insulin and review learning[5].	
Agree a review date in approximately 2 months, organise patient to have a HbA1c test and weight recorded before review.	
4. Review 3 months after starting insulin	**Tick**
Self-management of insulin injections and monitoring. How have they got on? Any issues or concerns?	
Travel advice with insulin, including a travel letter[5]. Diabetes UK.	
Review weight at 3 months. Discussion about weight since starting insulin.	
Progress with lifestyle goal.	
Check injection sites and how the individual has interpreted 'site rotation'.	
Progress with insulin adjustment. Note current dose in records. Have they reached their final fasting target range[3]? Have they reached 0.5 units / kg[3]? Does the insulin require intensification (advised to complete an intensive period of blood glucose monitoring and review the need for a bolus of 4 units of rapid-acting insulin before the meal with the highest post-meal blood glucose peak)[3]. Seek assistance if a rapid-acting insulin is required.	
Agree a review date. 3 months after an HbA1c if within target, or sooner if adjustments to insulin required.	
Feedback from individuals about the service offered and how they feel they have progressed since their treatment regimen change.	

References: 1. Toujeo SmPC. 2. Becker et al Diabetes Care 2015;38:637–643 | DOI: 10.2337/dc14-0006. 3. Davies M.J., Aroda V.R., Collins B.S et al. Management of Hyperglycaemia in Type 2 Diabetes, 2022. A consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), Diabetologia, Sept 2022. 4. DVLA and insulin website page Diabetes and driving - GOV.UK (www.gov.uk) Last Accessed: August 2023. 5. PITstop Handbook. 6. Toujeo SoloStar leaflet. 7. Trend Diabetes, Injection Technique Matters https://trenddiabetes.online/injection-technique-matters/ Last Accessed: August 2023. 8. PITstop insulin general rules PIT-stopA4posters_StudentPack_ed15with-GR.pdf (pitstopdiabetes.co.uk) Last Accessed: August 2023.

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

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

Presentation: Toujeo SoloStar pre-filled pens each ml contains 300 units of insulin glargine. SoloStar pen contains 1.5ml (450 units) of solution for injection. DoubleStar pen contains 3ml (900 units) of solution for injection.

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

Dosage and Administration: Toujeo is administered subcutaneously, by injection into the abdominal wall, the deltoid or the thigh, once daily, at any time of the day, preferably at the same time every day. The dose regimen (dose and timing) should be adjusted according to individual response. Injection sites must be rotated within a given injection area from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Do not administer intravenously. In type 1 diabetes mellitus, Toujeo must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements. In patients with type 2 diabetes mellitus, recommended daily starting dose is 0.2 units/kg followed by individual dose adjustments. Toujeo can also be given together with other anti-hyperglycaemic medicinal products. *Switch between insulin glargine 100 units/ml and Toujeo:* Insulin glargine 100 units/ml and Toujeo are not bioequivalent and are not directly interchangeable. When switching from insulin glargine 100 units/ml to Toujeo, this can be done on a unit-to-unit basis, but a higher Toujeo dose (approximately 10-18%) may be needed to achieve target ranges for plasma glucose levels. When switching from Toujeo to insulin glargine 100 units/ml, the dose should be reduced (approximately by 20%). *Switching from other basal insulins to Toujeo:* A change of dose and/or timing of the basal insulin and concomitant anti-hyperglycaemic treatment may be required. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia. Toujeo must not be mixed or diluted with any other insulin or other medicinal products. Close metabolic monitoring is recommended during a switch and in the initial weeks thereafter. SoloStar 1-80 units per single injection in steps of 1 unit and DoubleStar 2-160 units in steps of 2 units. When changing from Toujeo SoloStar to Toujeo DoubleStar, if the patient's previous dose was an odd number then the dose must be increased or decreased by 1 unit. Toujeo DoubleStar prefilled pen is recommended for patients requiring at least 20 units per day.

Special Populations: *Elderly, renal and hepatic impairment:* Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. *Paediatric:* When switching basal insulin to Toujeo, dose reduction of basal and bolus insulin needs to be considered on an individual basis, in order to minimise the risk of hypoglycaemia.

Contraindications: Hypersensitivity to insulin glargine or any excipients.

Precautions and Warnings: *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Toujeo is not the insulin of choice for treatment of diabetic ketoacidosis. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. *Hypoglycaemia:* In case of insufficient glucose control or a tendency to hyper/hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered. Particular caution should be exercised, and intensified blood glucose monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include patients in whom glycaemic control is markedly improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or who are elderly. The prolonged effect of subcutaneous insulin glargine may delay recovery from hypoglycaemia. *Intercurrent illness:* Requires intensified metabolic monitoring and often it is necessary to adjust the insulin dose. *Insulin antibodies:* administration may cause insulin antibodies to form. *Use with pioglitazone:* Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. *Medication errors:* Insulin labels must always be checked before each injection to avoid errors between Toujeo and other insulins. Patients must be instructed to never use a syringe to remove Toujeo from the SoloStar or DoubleStar pre-filled pen, A new sterile needle must be attached before each injection. Needles must not be re-used. ***Pregnancy and breast-feeding:*** There is no data from exposed pregnancies in controlled clinical trials. However, there is a large amount of data on use of insulin glargine 100 units/ml in pregnant women indicating no specific adverse effects on pregnancy and no specific malformative nor feto/neonatal toxicity. The use of Toujeo may be considered during pregnancy, if clinically needed. Careful monitoring of glucose control is essential. It is unknown if insulin glargine is excreted in breast milk. ***Interactions:*** Substances that affect glucose metabolism may require adjustment of insulin glargine.

Adverse Reactions: *Very common:* Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. *Common:* Lipohypertrophy, injection site reactions, including redness, pain, itching, hives, swelling, or inflammation. *Not known:* Cutaneous amyloidosis. *Prescribers should consult the SmPC in relation to other adverse reactions.*

GB List Price: SoloStar 3 x 1.5ml pens: £32.14; DoubleStar 3 x 3ml pens: £64.27

Legal Category: POM

M**arketing Authorisation Number**: SoloStar 3 Pen pack: PLGB 04425/0817; DoubleStar 3 Pen pack: PLGB 04425/0818.

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

Further information is available from: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.

Date of preparation: September 2022.

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.
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SmPC date: 01 Jan 2021

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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.

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SPC date: 09 July 2020