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Starting Toujeo (insulin glargine 300 units/mL) when GLP-1 RA are not suitable

This presentation has been organised and funded by Sanofi
Adverse event reporting and prescribing information is available at the
end of this presentation or upon request

MAT-XU-2303352 (v2.0) | August 2023

Structure

- 1 Guidelines & SPS
- 2 Patient Information (case study)
- 3 Practicalities of starting Toujeo
- 4 Resources to support (external & Sanofi)

Guidelines & Specialist Pharmacy Service Recommendations

Rescue therapy

For symptomatic hyperglycaemia, consider insulin or a sulfonylurea and review when blood glucose control has been achieved.

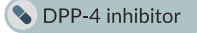


Treatment options if further interventions are needed

At any point

HbA1c not controlled below individually agreed threshold

Switching or adding treatments





Consider:

 DPP-4 inhibitor **or**  Pioglitazone
or  Sulfonylurea

SGLT2 inhibitors may also be an option in dual therapy:

 TA 315 Canagliflozin **or**  TA 288 Dapagliflozin
 TA 336 Empagliflozin **or**  TA 572 Ertugliflozin

Or in triple therapy:

 TA 315 Canagliflozin **or**  TA 418 Dapagliflozin
 TA 336 Empagliflozin **or**  TA 583 Ertugliflozin

At any point

Cardiovascular risk or status change

If the person has or develops chronic heart failure or established atherosclerotic CVD


Switching or adding treatments

Offer
An SGLT2 inhibitor (if not already prescribed)

If the person has or develops a high risk of CVD (QRISK2 of 10% or higher)

Switching or adding treatments

Consider
An SGLT2 inhibitor (if not already prescribed)

Established atherosclerotic CVD includes coronary heart disease, acute coronary syndrome, previous myocardial infarction, stable angina, prior coronary or other revascularisation, cerebrovascular disease (ischaemic stroke and transient ischaemic attack) and peripheral arterial disease. 




At each point follow the prescribing guidance.

Switch or add treatments from different drug classes up to triple therapy (dual therapy if metformin is contraindicated).

In February 2022, using ertugliflozin to reduce cardiovascular risk when blood glucose is well controlled was off label. See [NICE's information on prescribing medicines](#).

Insulin therapy

When dual therapy has not continued to control HbA1c to below the person's individually agreed threshold, also consider insulin-based therapy (with or without other drugs).

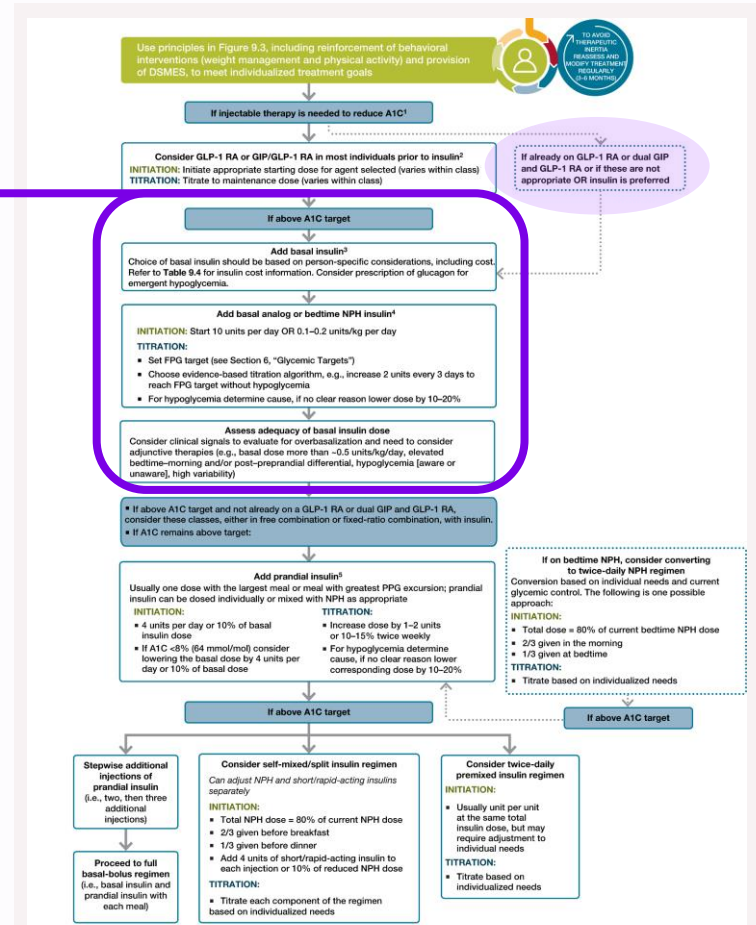
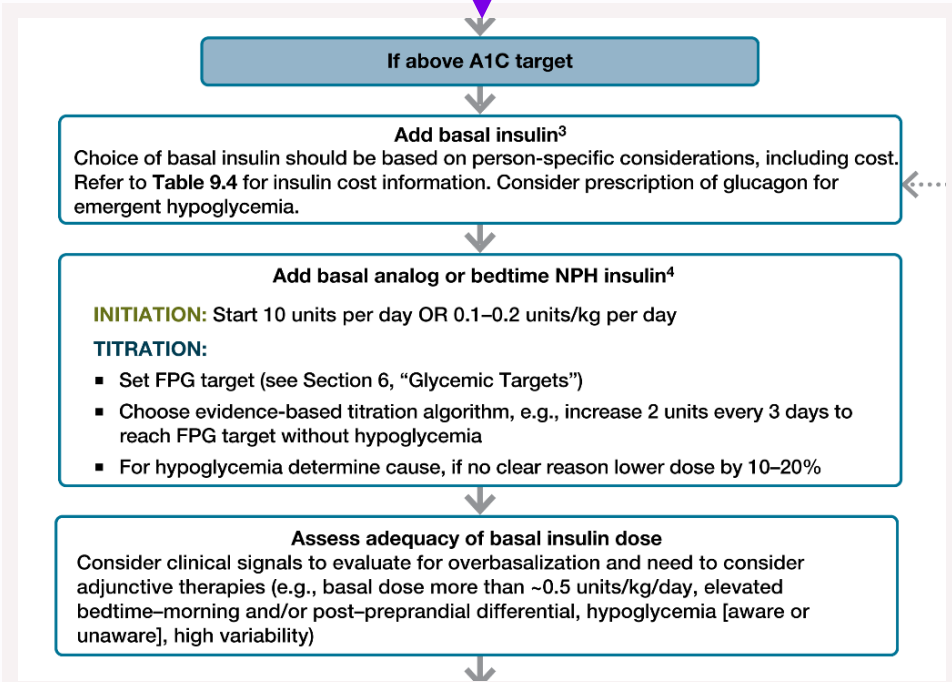
 TA 288 Dapagliflozin **or**  TA 336 Empagliflozin
 TA 315 Canagliflozin

GLP-1 mimetic treatments

If triple therapy with metformin and 2 other oral drugs is not effective, not tolerated or contraindicated, consider triple therapy by switching one drug for a GLP-1 mimetic for adults with type 2 diabetes who:

- have a body mass index (BMI) of 35 kg/m² or higher (adjust accordingly for people from Black, Asian and other minority ethnic groups) and specific psychological or other medical problems associated with obesity **or**
- have a BMI lower than 35 kg/m² and:
 - for whom insulin therapy would have significant occupational implications **or**
 - weight loss would benefit other significant obesity related comorbidities.

American Diabetes Association (ADA) Standards of Care in Diabetes - 2023



1. Consider insulin as the first injectable if evidence of ongoing catabolism, symptoms of hyperglycemia are present, when A1C levels (>10% [86 mmol/mol]) or blood glucose levels (>300 mg/dL [16.7 mmol/L]) are very high, or a diagnosis of type 1 diabetes is a possibility.
2. When selecting GLP-1 RA, consider individual preference, A1C lowering, weight lowering effect, or frequency of injection. If CVD is present, consider GLP-1 RA with proven CVD benefit. Oral or injectable GLP-1 RA are appropriate.
3. For people on GLP-1 RA and basal insulin combination, consider use of a fixed-ratio combination product (Duple.Ira or Glar.Lira).
4. Consider switching from evening NPH to a basal analog if the individual develops hypoglycemia and/or frequently forgets to administer NPH in the evening and would be better managed with an A.M. dose of a long-acting basal insulin.
5. If adding prandial insulin to NPH, consider initiation of a self-mixed or premixed insulin regimen to decrease the number of injections required.

Case Study

Case study: Starting Toujeo when once-daily oral or injectable GLP-1 Receptor Agonist (GLP-1 RA) are not suitable



Ishir

- Age 42
- Asian Indian British ethnic group
- Lives alone
- Unemployed

- Duration of diabetes 3 years. Has a Group 1 licence but no car at present.
- BMI 31.7. eGFR > 90ml/min/1.73m². Urine ACR below detectable levels. CKD G1A1. LFTs not checked.
- No retinopathy, BP 154/82mm Hg, cholesterol 5.6 mmol/L, triglycerides 3.4mmol/L, non-HDL cholesterol 4.5 mmol/L

Year	Comments	Diabetes meds	HbA1c (mmol/mol)	Weight (kg)
Feb 2020	Didn't want any medication. No referral to structured education	Diet only	49 and 52	98
Sept 2021	Not seen for 19 months due to lockdown. Sedentary, apart from work / comfort eating	Metformin started and titrated up to 500mg x 2 a.m. and 500mg p.m.	68	96
Feb 2022	Made redundant from garden centre job	Dapagliflozin added 2021	59 → 56	93 → 89
Feb 2023	Low in mood. Comfort eating. Osmotic symptoms related to hyperglycaemia	Gliclazide 80mg added and now taking 120mg twice daily	78 → 65 (July 2023)	94 → 95

Important to consider

Ishir's HbA1c trajectory

His 3-year duration of diabetes (importance of maintaining tight glycaemic control around 53mmol/mol to avoid complications related to diabetes)

Young-onset type 2 diabetes (diagnosed under the age of 40). Important to be pro-active treating-to-target with all cardiovascular risk parameters. Also important to listen to Ishir and understand his relationship with food and his weight. May require psychological support

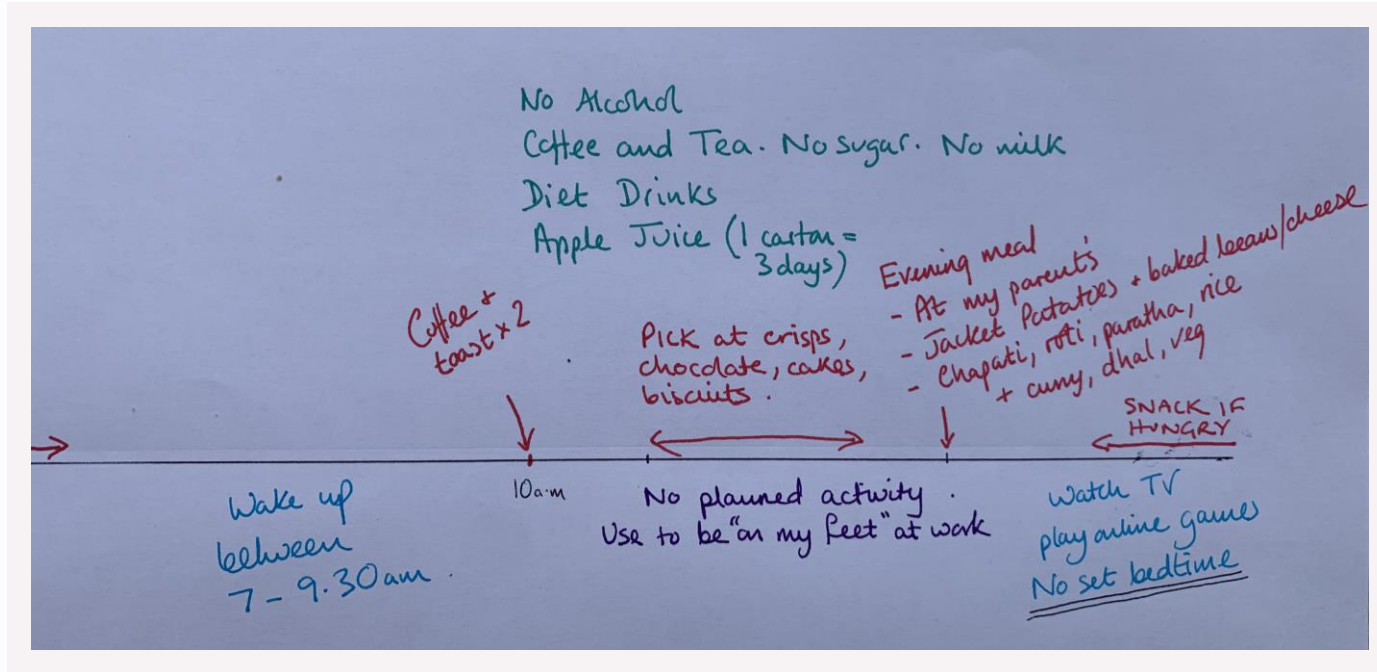
Concordance with current oral medications. Could simplify and escalate doses

The way he currently lives his life

Unsure if currently monitoring his blood glucose.

Not driving.

Timeline: "Talk me through a normal working day"



Optimise doses of current oral meds and consider additional medications relevant to the individual

1. Review current medication: concordance and dose

Solution: discuss use of modified-release Metformin 1g tablets taken together and swapping to a once daily Sulfonylurea

2. Use the medication in class with best efficacy for HbA1c and weight reduction.

Solution: swap to Canagliflozin 100mg ready to increase to 300mg if tolerated eGFR > 60ml/min/1.73 m²

3. Adding additional oral medication

- Pioglitazone is an option (15 – 30mg).
- Worth checking for NAFLD and would help tackle abnormal lipid profile
- DPP-4 inhibitor (Gliptin) unlikely to achieve HbA1c reduction required³

4. Start basal insulin

- Really keen to take all medication in the morning due to concordance issues in the evening
- Humulin I needs to be taken before bed to fix the fasting blood glucose
- Varied lifestyle and no set bedtime so preferred Toujeo with the three-hour window either side of the injection
timewhen needed Toujeo can be taken in the morning with the aim to fix the fasting blood glucose
- START TOUJEO. CONTINUE Metformin and SGLT-2 inhibitor stop his Sulfonylurea, if on Pioglitazone, 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
- The recommended daily starting dose is 0.2 units/kg followed by individual dose adjustments. The dose regimen (dose and timing) should be adjusted according to individual response

Zaccardi F. et al. Efficacy and safety of sodium-glucose co-transporter-2 inhibitors in type 2 diabetes mellitus: systematic review and network meta-analysis *Diabetes, Obesity and Metabolism*, 2016;18:783–794.

Goodchild A. Summary of Oral Diabetes Medications, edition 18, DIME Square Ltd

Oral agents and insulin

NICE¹

- Continue to offer metformin (if no contraindications or intolerance).
- Review the continued need for other blood glucose lowering therapies (an SGLT-2i in combination with insulin is an option)

Stop medicines that have had no impact on glycaemic control or weight, unless there is an additional clinical benefit, such as cardiovascular or renal protection, from continued treatment

ADA / EASD²

- Add basal insulin to existing pharmacological therapies
- Agents that cause hypoglycaemia in themselves, such as Sulfonylureas, should be **discontinued**

1. NICE (2015, updated June 2022) NG28, *Type 2 Diabetes in adults: management* www.nice.org.uk/Guidance/NG28 Accessed: July 2023.
2. 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, <https://doi.org/10.1007/s00125-022-05787-2> Accessed: July 2023.

Starting Toujeo

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Initiation of Toujeo



Toujeo is a basal insulin for once-daily administration 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



In patients with type 2 diabetes mellitus, Toujeo can also be given together with other anti-hyperglycaemic medicinal products



The recommended daily starting dose is 0.2 units/kg followed by individual dose adjustments



Adherence of the patient to the dose and dietary regimen, correct insulin administration and awareness of hypoglycaemia symptoms are essential to reduce the risk of hypoglycaemia

Starting Toujeo SoloStar: resources to help

Toujeo SoloStar Handbook



SoloStar Insulin Passport

Name:

Date of birth:

NHS Number:

Emergency Contact:

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I have diabetes
and use Toujeo® SoloStar®
(insulin glargine 300 units/mL)

Other Insulins:

Other Medication:

Reporting of side effects

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly: In the UK, via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. In Ireland, at www.hpra.ie; email medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

Sanofi Medical Information Line Freephone 08000 35 25 25

If your insulin prescription is changed, please destroy this card and collect a replacement.

Date of preparation: May 2022
This item is intended for patients.
MAT-XU-2200796(v1.0)



1. Patient resources: <https://www.mysanofiinsulin.co.uk/home/> Accessed: July 2023.
2. Healthcare professional education and resources <https://www.campus.sanofi/uk/products/diabetes/toujeo> Accessed: July 2023.
3. Get in touch for details of your local Sanofi representative or to order patient literature or dummy devices <https://www.campus.sanofi/uk/science/get-in-touch> Accessed: July 2023.



Notifying the DVLA - Patients will need to be taught blood glucose monitoring

Treatment	Group 1	Group 2
Diabetes managed by diet / lifestyle	X	X
Managed by medication not associated with hypoglycaemia (Metformin, Pioglitazone, DPP-4i, SGLT-2i, GLP-1 RA)	X	✓
Managed by tablets causing a hypoglycaemia risk (Sulphonylureas and Glinides)	X	✓
Diabetes treatment with insulin	✓	✓

X No need to notify providing there are no other disqualifying complications (e.g. vision, sensation, circulation)

Resources available for Health Care Professionals and Patients

Social Prescribing link workers

- Connect people to community-based support, including activities and services that meet practical, social, and emotional needs that affect their health and wellbeing. This includes connecting people to statutory services for example housing, financial and welfare advice
- Work collaboratively across the health and care system, targeting populations with greatest need and risk of health inequalities. They collaborate with partners to identify gaps in provision and support community offers to be accessible and sustainable
- Social prescribing works particularly well for people with low level mental health needs, who feel lonely or isolated, with long term conditions and complex social needs

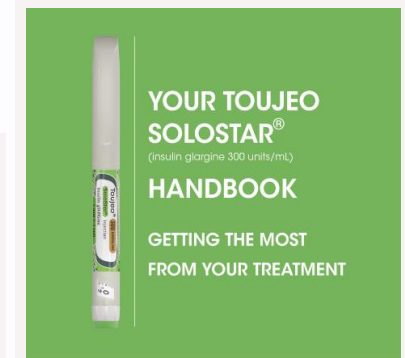


Resources to support starting insulin



Find resources and support for your patients on Sanofi products.

www.mysanofiinsulin.co.uk/home



Programme for injectable therapy for type 2 diabetes, 10th edition. A guide for patients during the assessment stage and the initial 6-months follow-up and other useful resources

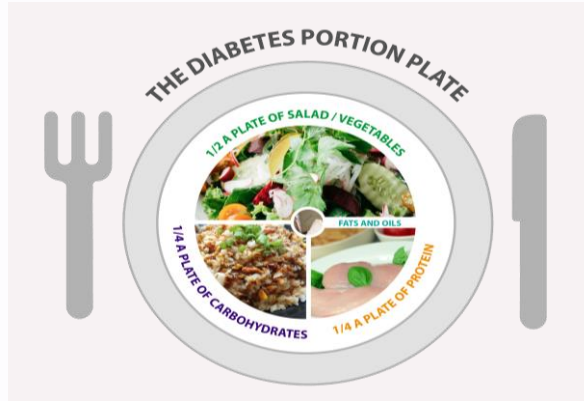
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Trend Diabetes Injection Technique Matters resources <https://trenddiabetes.online/injection-technique-matters/> Accessed: July 2023.

<https://www.diabetes.org.uk/guide-to-diabetes/managing-your-diabetes/treating-your-diabetes/insulin>

<https://diabetesonthenet.com/> Accessed July 2023

Resources to help discuss his timeline and agree a lifestyle goal and action plan



Better Health Let's do this **NHS**

Loss weight Quit smoking Get active Drink less

Kickstart your health

Healthy changes start with little changes. Whether you want to lose weight, get active or quit smoking, Better Health is here with lots of free tools and support. You can also find advice apps to fit your mood with Every Mind Matters.

There has never been a better time to kickstart your health. Let's do this!

Lose weight

Losing weight is not about getting it right – it's about getting started. Making small, simple changes can really help you shed the pounds. Get started today with our tips, support and special offers.

Get active

No matter how active you are, physical activity is good for your body and mind. Aim to be active every day, the more you do the better you'll feel. Try these tools, tips and special offers to get active and move more.

Quit smoking

Smoking weakens our lungs and makes it harder to breathe. Check out the free tools and tips available and join millions who have successfully quit smoking.

Drink less

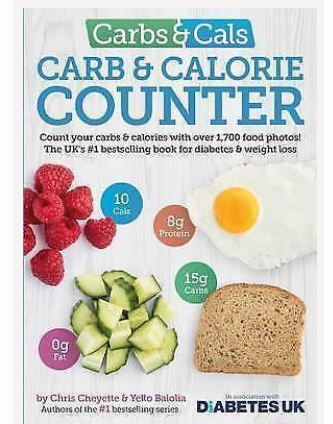
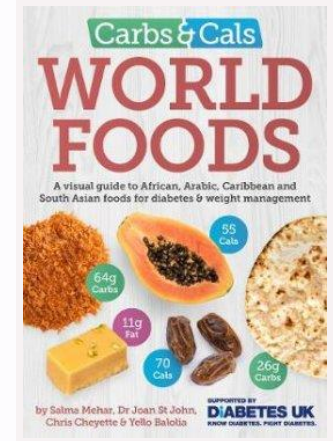
Drinking less can help you feel a bit better every day – and it's easier to make a change than you think. We have some simple tips and tools to help you start cutting down today.

Take care of your mind

Looking after your mind is just as important as looking after your body, but it can be easily overlooked.

Every Mind Matters has lots of expert advice and practical tips to help you stay on top of your mental wellbeing.

➔ Visit Every Mind Matters



Carbs & Cals website, books and App

NHS Better Health website, including access to the Active 10 App <https://www.nhs.uk/better-health/> Accessed July 2023

NHS Every Mind Matters website <https://www.nhs.uk/every-mind-matters/> Accessed July 2023

NHS England digital weight loss Programme

12-week programme
Requires a practice or pharmacy referral

Who can be referred to the programme?

- Over 18
- BMI 30 or more (≥ 27.5 for people from black, Asian, and ethnic minority backgrounds)
- Have diabetes (type 1 or type 2), high blood pressure, or both.
- Have a smartphone, tablet, or computer with internet access

Excluded: moderate/severe frailty, pregnant, eating disorder, bariatric surgery in last 2 years



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 foeto/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 **Marketing 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. Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to UK-drugsafety@sanofi.com

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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](mailto:medicalinformation@sanofi.com).

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