Stopping a once-weekly GLP-1 Receptor Agonist (GLP-1 RA) and starting Toujeo (insulin glargine 300 units/mL)

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-2303350 (v2.0) | July 2023

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Diabetes Specialist Nurse and lead PITstop trainer

Disclaimer

In the last 5 years I have acted as a paid speaker for Napp and Sanofi

I have received payments from Sanofi for delivering PITstop courses to primary care healthcare professionals

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Structure

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

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Guidelines & Specialist Pharmacy Service Recommendations

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Specialist Pharmacy Service

The first stop for professional medicines advice

Prescribing available insulins

Published 6 July 2023 · Last updated 7 July 2023 · See all updates

Topics: Diabetes · Supply

Current supply disruption of GLP-1 receptor agonists means some patients may need to switch to insulin. Prescribers must know which insulins can be used.

Switching from GLP-1 receptor agonists to insulin

Switching from GLP-1 receptor agonists to insulin may be necessary. Recommendations for insulin in this cohort are suggested to ensure supply chains remain stable for the whole population of people with type 1 and type 2 diabetes requiring insulin.

Insulin choice

It is recognised that insulin prescribing is undertaken by healthcare professionals who are competent and confident in insulin initiation and titration, where many factors may influence the decisions to prescribe a particular type of insulin (eg. Basal, Mixed, Intermediate).

The following insulins are currently able to support insulin initiation at the volumes required across the UK as part of the review of patients unable to obtain GLP-1 receptor agonnists. Supply content is maintained by DHSC.

Basal insulin

Able to support switching

First line

- Toujeo 300 units/mL SoloStar, solution for injection

Second line

- Abasaglar 100 units/mL KwikPen solution for injection

Unable to support switching

- Lantus (insulin glargine) 100 units/mL solution for injection
- Semglee (insulin glargine) 100 units/mL solution for injection
- Levemir (insulin detemir) 100 units/mL solution for injection
- Tresiba (insulin degludec) 100 units/mL solution for injection
- Tresiba (insulin degludec) 200 units/mL solution for injection

Intermediate-acting insulin

Able to support switching

- Humulin I KwikPen (insulin isophane) 100 units/mL suspension for injection

Unable to support switching

- Insulatard (insulin isophane) 100 units/mL suspension for injection

Mixed insulin

Able to support switching

- Humulin M3 KwikPen (biphasic insulin isophane) 100 units/mL suspension for injection

Unable to support switching

- Humalog Mix25 (biphasic insulin lispro) 100 units/mL suspension for injection
- Humalog Mix50 (biphasic insulin lispro) 100 units/mL suspension for injection
- Novomix 30 (biphasic insulin aspart) 100 units/mL suspension for injection

www.sps.nhs.uk/articles/prescribing-available-insulins Accessed July 2023

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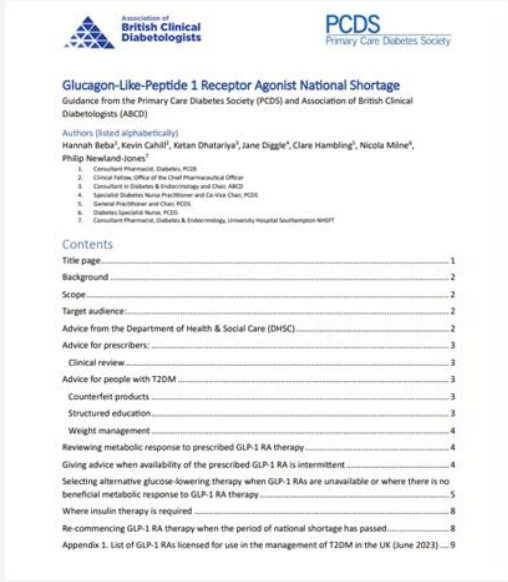
National guidance regarding GLP-1 RA shortage and use of insulin

Where insulin therapy is clinically indicated, clinicians are advised to initiate insulin in line with principles of NICE NG28.

It is important to note that specific brands of insulin mentioned within NICE NG28 are unlikely to be able to take a large uplift in prescribing, therefore any decisions on insulin brand choice should be based on ongoing insulin availability noted within the SPS supply tool

The choice of insulin should take account of individual characteristics and the clinical needs of the person with T2DM. Where possible, utilise the full range of insulins and devices available to reduce the risk of further impacting supply chain issues.



Association of British Clinical Diabetologists

PCDS Primary Care Diabetes Society

Glucagon-Like-Peptide 1 Receptor Agonist National Shortage

Guidance from the Primary Care Diabetes Society (PCDS) and Association of British Clinical Diabetologists (ABCD)

Authors (listed alphabetically)

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Contents

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Joint statement from ABCD and PCDS. Glucagon-Like-Peptide 1 Receptor Agonist National Shortage. Guidance from the Primary Care Diabetes Society (PCDS) and Association of British Clinical Diabetologists (ABCD). https://diabetesonthenet.com/wp-content/uploads/PCDS_ABCD-GLP-1-RA-shortage_20230628.pdf Accessed: July 2023.

NICE NG28: Recommendations | Type 2 diabetes in adults: management | Guidance | NICE Accessed: July 2023.

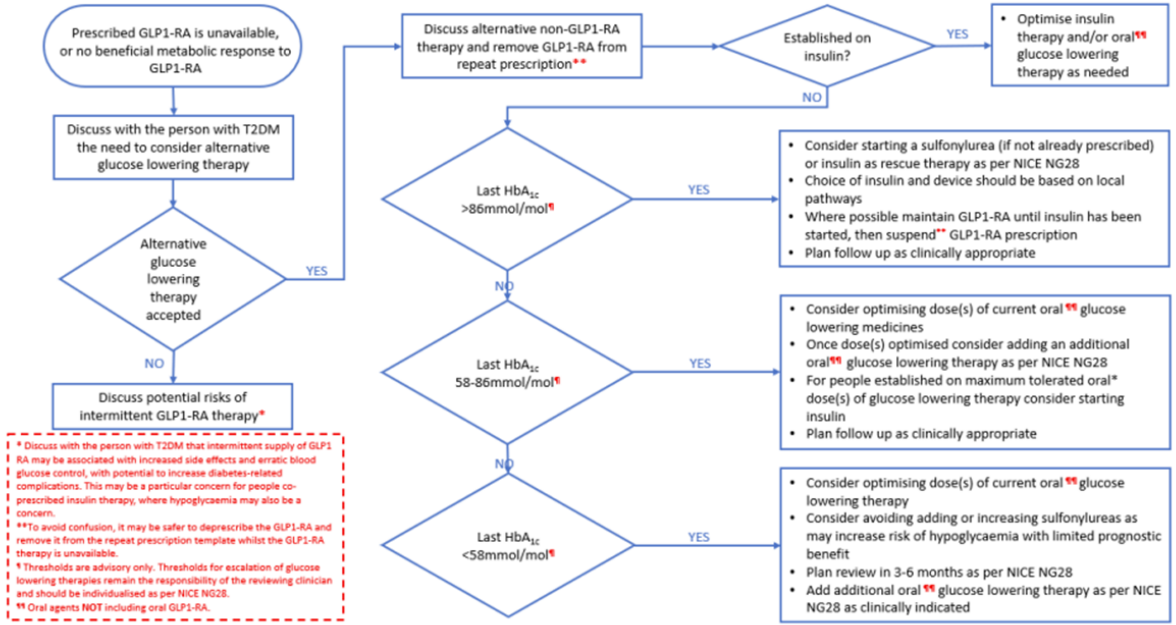
SPS supply tool: https://www.sps.nhs.uk/home/tools/medicines-supply-tool Accessed: July 2023.

Association of British Clinical Diabetologists

PCDS Primary Care Diabetes Society

Selecting alternative glucose-lowering therapy when GLP-1 RAs are unavailable or where there is no beneficial metabolic response to GLP-1 RA therapy

Figure 1. Choosing alternative glucose-lowering therapies in T2DM when GLP-1 RAs are unavailable or there is no beneficial metabolic response.



Note: Symptomatic hyperglycaemia may indicate clinical need for insulin therapy. If in doubt, discuss with specialist. Symptoms of hyperglycaemia include polyuria, polydipsia, weight loss and fatigue. Think 4Ts – Thirst, Toilet, Thinner, Tired.

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How to choose further medicines

NICE National Institute for Health and Care Excellence

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
- TA 288 Dapagliflozin
- TA 336 Empagliflozin
- TA 572 Ertugliflozin

Or in triple therapy:

- TA 315 Canagliflozin
- TA 418 Dapagliflozin
- TA 336 Empagliflozin
- 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
- 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/m^2 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/m^2 **and**:
  - for whom insulin therapy would have significant occupational implications **or**
  - weight loss would benefit other significant obesity related comorbidities.

Published date: February 2022. This is a summary of the advice in the NICE guideline on type 2 diabetes in adults: management.

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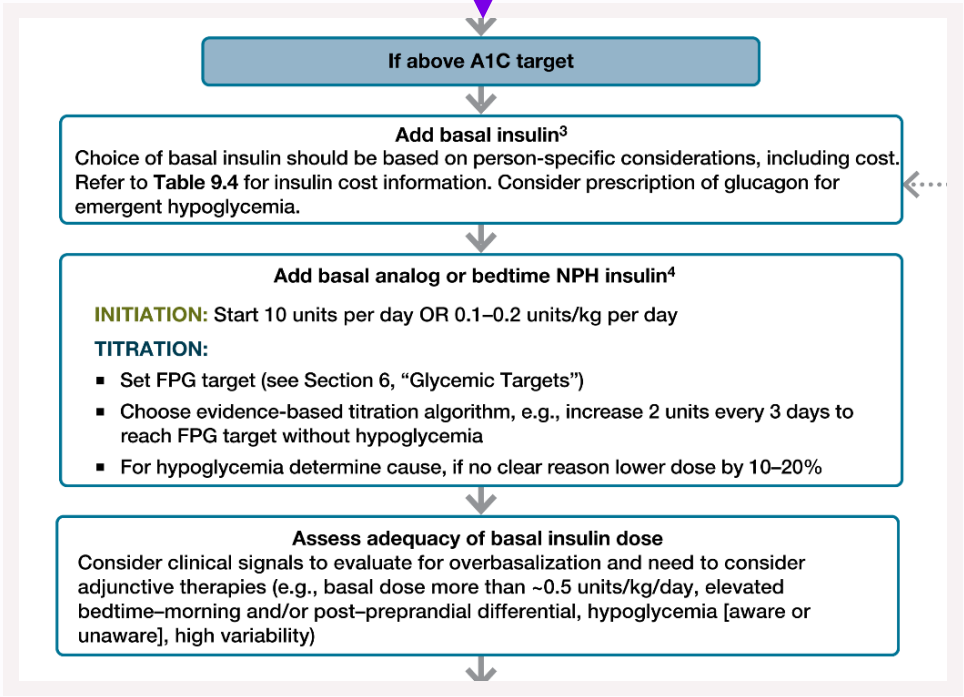
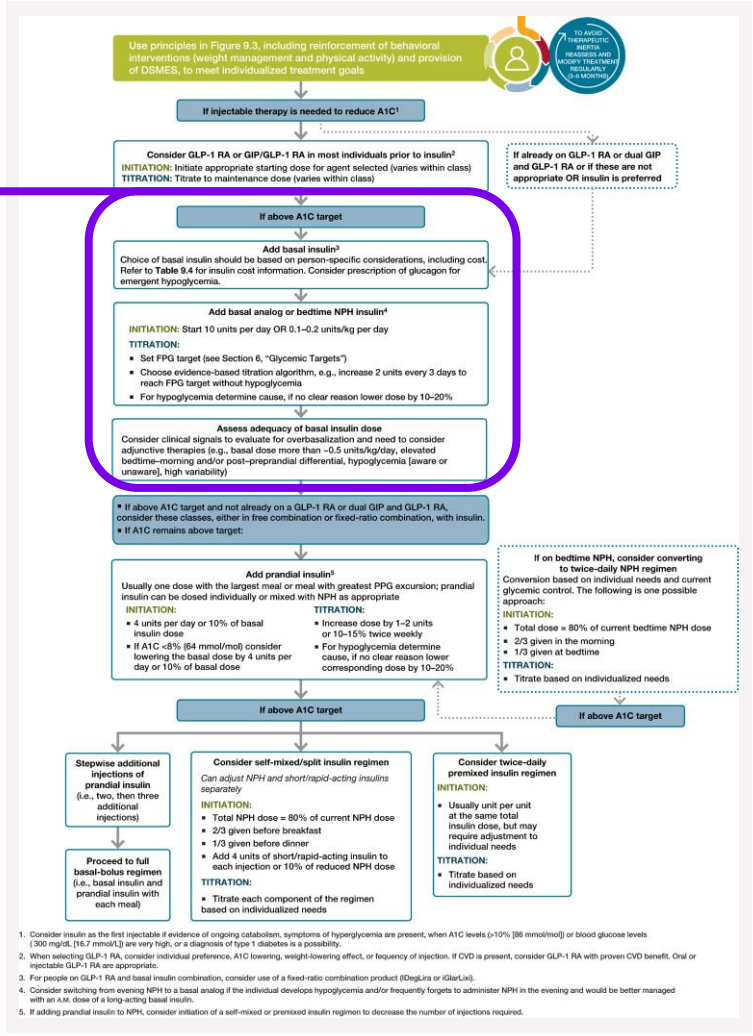
American Diabetes Association (ADA) Standards of Care in Diabetes - 2023





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ADA. Chapter 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes - 2023. Diabetes Care. 2023;46 (Supplement_1): S140-S157. doi:10.2337/dc23-S009

Case Study

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Case study: Stopping a once-weekly GLP-1 Receptor Agonist (GLP-1 RA)* and starting Toujeo insulin

Dave

- Age 57
- Lives alone

- Duration of diabetes 6 years. Group 1 driver (has a group 2 license but not actively using it)
- BMI 42. Weight 136kg. eGFR 76 ml/min/1.73 m^2. Urine ACR 2.8 U/L. ALT 57mg/mmol. Background retinopathy both eyes, degree of sensory neuropathy in both feet

Oral diabetes medication

- Metformin 1g with breakfast, 1g with evening meal
- Empagliflozin 25mg
- Gliclazide 160mg twice daily

Year	Semaglutide dose	HbA1c (mmol/mol)	Weight (kg)
2017		96	140
2018	0.25mg → 0.5mg	99 → 82 → 72	143 → 138 → 134
2021	0.5mg → 1mg	76 → 67	136 → 129
2023	1mg	74	136

*This case study applies to patients taking any dose of Dulaglutide (Trulicity®), Semaglutide (Ozempic®▼) and Exenatide prolonged-release (Bydureon®)

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Treatment Options

Option 1:

Discuss with Dave that intermittent supply of their GLP-1 RA may be associated with increased side effects and erratic blood glucose control, with potential to increase diabetes- related complications

Option 2:

- Consider optimising Dave's current oral glucose lowering medications
- Once doses optimised, consider adding an additional oral glucose lowering therapy as per NICE NG28
- For people established on maximum oral dose(s) consider starting insulin
- Plan follow-up as clinically appropriate

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Joint statement from ABCD and PCDS. Glucagon-Like-Peptide 1 Receptor Agonist National Shortage. Guidance from the Primary Care Diabetes Society (PCDS) and Association of British Clinical Diabetologists (ABCD). June 2023. https://diabetesonthenet.com/wp-content/uploads/PCDS_ABCD-GLP-1-RA-shortage_20230628.pdf Accessed: July 2023

Important to consider

- Dave's HbA1c and weight trajectory
- His 6-year duration of diabetes (still time to achieve a protective HbA1c of 53mmol/mol. All above 67mmol/mol since 2017 (not protective from microvascular and macrovascular complications), so wise to escalate treatment rather than rely on intermittent supply of GLP-RA
- Concordance with current oral medications and escalation of doses (with the option to simplify to once daily)
- The way he currently lives his life
- If he has Non-Alcoholic Fatty Liver Disease (NAFLD)
- Check the current Out of Stock information and advice on SPS website

Joint statement from ABCD and PCDS. Glucagon-Like-Peptide 1 Receptor Agonist National Shortage. Guidance from the Primary Care Diabetes Society (PCDS) and Association of British Clinical Diabetologists (ABCD). https://diabetesonthenet.com/wp-content/uploads/PCDS_ABCD-GLP-1-RA-shortage_20230628.pdf Accessed: July 2023.

www.sps.nhs.uk/articles/prescribing-available-insulins/ Accessed: July 2023

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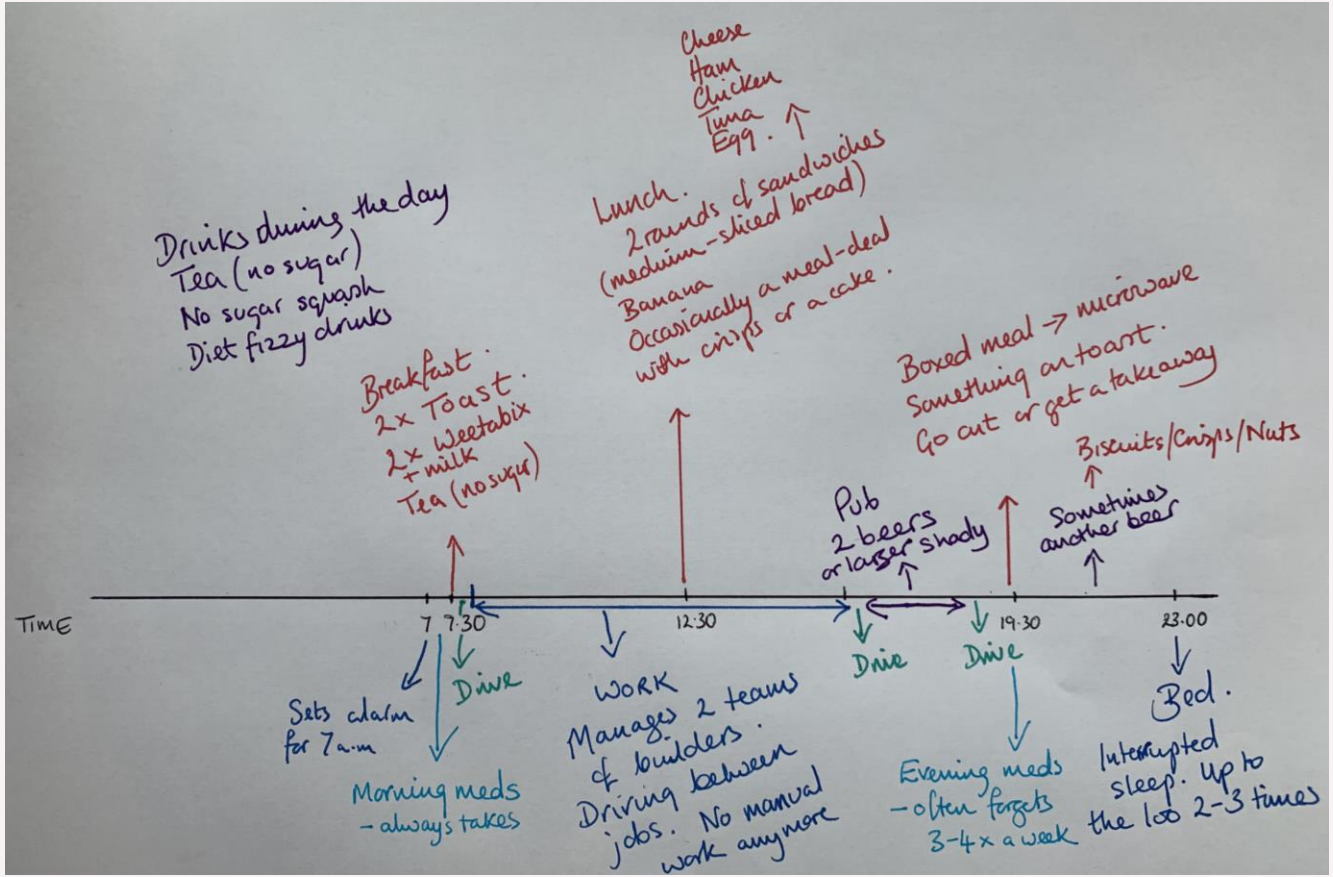
Timeline: “Talk me through a normal working day”



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

1. Often missing evening doses (Metformin 1g and Gliclazide 80mg)
   Solution: discuss use of modified-release versions taken in the morning

2. Use the medication in class with best efficacy for HbA1c and weight reduction.
   Solution: on higher dose of Empagliflozin already

3. Adding additional oral medication
   - Already taking triple oral therapy
   - Pioglitazone may be relevant especially if a diagnosis of NAFLD confirmed.
   - Quadruple oral therapy is an option during the GLP-1 shortage

4. Start basal insulin
   - Humulin I and Toujeo available options. Likely to need a large dose (> 60units based on weight so Toujeo a sensible option
   - 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

Joint statement from ABCD and PCDS. Glucagon-Like-Peptide 1 Receptor Agonist National Shortage. Guidance from the Primary Care Diabetes Society (PCDS) and Association of British Clinical Diabetologists (ABCD). https://diabetesonthenet.com/wp-content/uploads/PCDS_ABCD-GLP-1-RA-shortage_20230628.pdf Accessed: July 2023.
NICE (2015, updated June 2022) NG28, *Type 2 Diabetes in adults: management* www.nice.org.uk/Guidance/NG28 Accessed: June 2023.
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: June 2023.

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Oral agents and insulin

NICE[1]

- 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 / EASD[2]

- 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.

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Starting Toujeo

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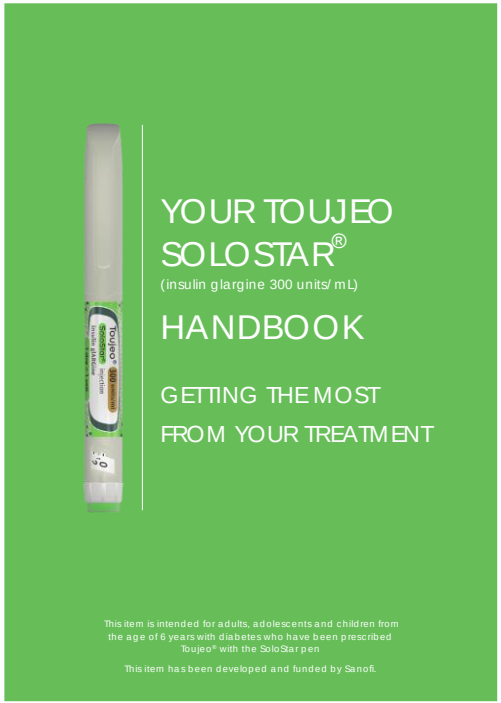
Initiation of Toujeo

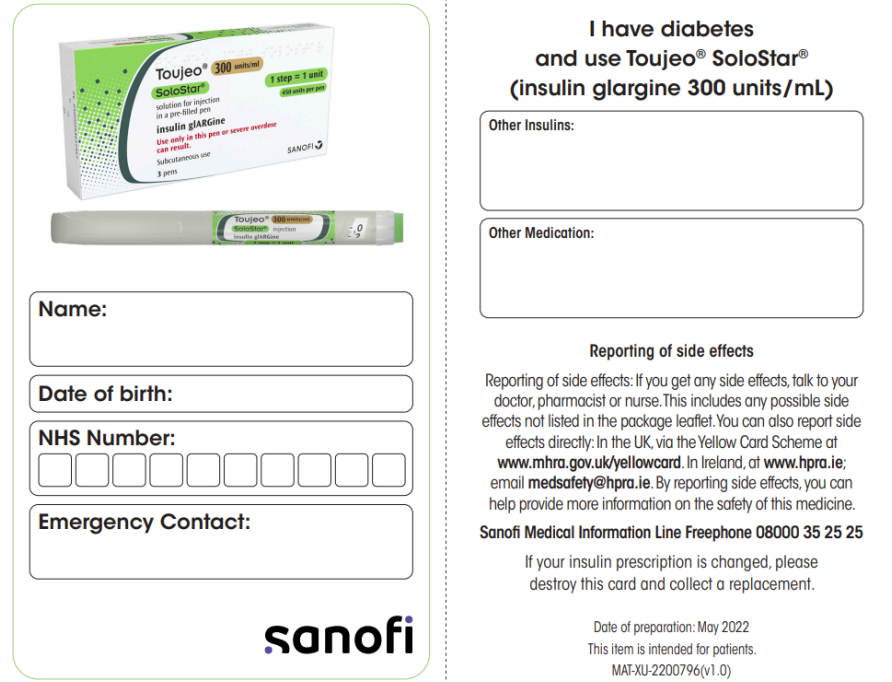
- Toujeo is a basal insulin for once-daily administration at any time of the day, preferably at the same time every day
- The dose regimen (dose and timing) should be adjusted according to individual response
- In patients with type 2 diabetes mellitus, Toujeo can also be given together with other anti-hyperglycaemic 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



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.

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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)

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Resources available for Health Care Professionals and Patients

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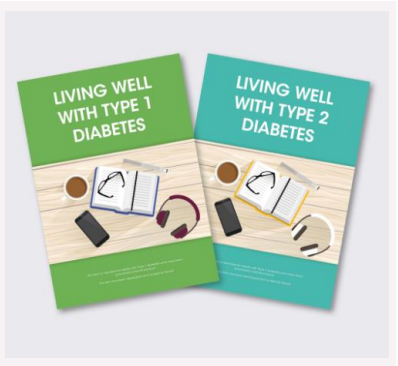
Resources to support starting insulin

Find resources and support for your patients on Sanofi products.

www.mysanofiinsulin.co.uk/home

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

Diabetes ONTHENET.com



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

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

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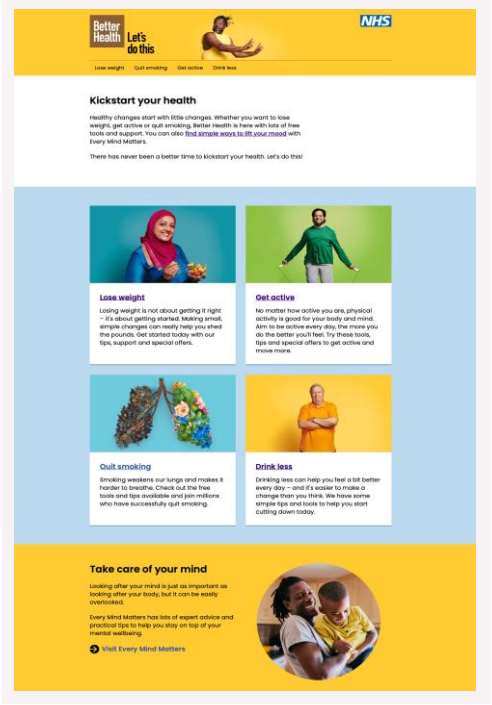
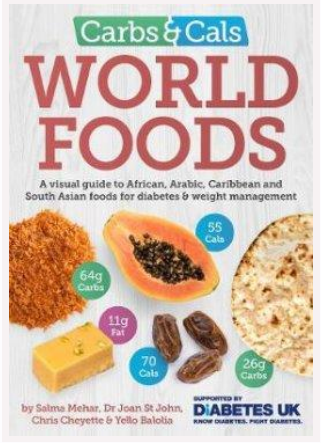
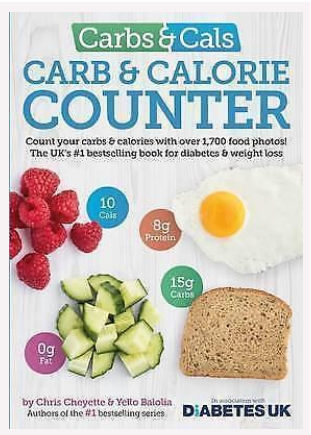
Resources to help discuss her timeline and agree a lifestyle goal and action plan







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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

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www.england.nhs.uk/digital-weight-management/how-to-access-the-programme/ Accessed July 2023

GB

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. 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

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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.

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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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