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MAT-GB-2002595 (v1.0) - September 2020

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CPD credits have been applied for this series of webinars.
Feel free to attend all or just a selection of the sessions. Please note that to be eligible for CPD point, you will need to attend a minimum of 1 hour of the live event.

16:00 – 16:10 Opening Remarks – Chairs

Professor Michael Feher - *Consultant Physician in Diabetes & Clinical Pharmacology, Chelsea & Westminster Hospital NHSFT*
Dr. David Hopkins - *Diabetologist, Director, Clinical Academic Lead Diabetes, Endocrinology & Obesity Institute and Network. KCL*

16:10 – 16:40 Management of Diabetes and Medical specialities in the current environment

Dr. Steve Thomas - *Consultant in Diabetes, GSTT NHSFT; Clinical Director, London Diabetes Clinical Network*

16:40 – 17:10 The How & Why of Nonsurgical Weight-Loss induced Remission of Type 2 Diabetes – ADA Lecture

Professor Roy Taylor - *Professor of Medicine and Metabolism, Director, Newcastle MRC, Newcastle University*

17:10 – 17:40 Exploring Destinations for People Living with Type 2 Diabetes – Fixed Ratio Combinations

Professor Steve Bain - *Professor in Medicine (Diabetes) & Clinical Lead for Diabetes Research Networks, Wales*

17:40 – 18:00 Utilising technology to optimise seasonal flu vaccine uptake in persons with diabetes

Dr. Naresh Kanumilli - *Diabetes Network Lead for Greater Manchester & East Chesire. Primary Care research lead GMCRN*

18:10 -18:30 Panel Discussion & Close

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Focus on Hypoglycaemia

16:00 – 16:10 Opening Remarks – Chairs
Professor Michael Feher - *Consultant Physician in Diabetes & Clinical Pharmacology, Chelsea & Westminster Hospital NHSFT*
Dr. David Hopkins - *Diabetologist, Director, Clinical Academic Lead Diabetes, Endocrinology & Obesity Institute and Network. KCL*

16:10 -16:30 Where do PCSK9 inhibitors fit into current treatment guidelines
Dr. Handrean Soran - *Consultant Physician and Endocrinologist, Manchester Royal Infirmary*

16:30 – 16:50 Hypoglycaemia Definitions
Professor Stephanie Amiel - *RD Lawrence Professor of Diabetic Medicine, Kings College London*

16:50 – 17:10 Technology alone is not the answer to hypoglycaemia
Dr. Emma Wilmot - *Diabetologist, University Hospitals of Derby & Burton; Hon Assistant Professor, University of Nottingham*

17 10 – 17:40 The second-generation basal insulins a review of clinical outcomes and hypoglycaemia profiles
Professor Steve Bain - *Professor in Medicine (Diabetes) &Clinical lead for Diabetes Research Networks, Wales*

17:40 – 18:10 The Role of Technology in preventing and managing hypoglycaemia
Professor Richard Bergenstal - *Executive Director, International Diabetes Centre. Clinical Professor, University of Minnesota*

18:00 -18:30 Panel Discussion & Close

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Focus on The Multidisciplinary Team

16:00 – 16:10 **Opening Remarks – Chairs**
Professor Michael Feher - *Consultant Physician in Diabetes & Clinical Pharmacology, Chelsea & Westminster Hospital NHSFT*
Dr. David Hopkins - *Diabetologist, Director, Clinical Academic Lead Diabetes, Endocrinology & Obesity Institute and Network. KCL*

16:10 – 16:40 **Implementation of a Dedicated PCSK9i Service in a UK Tertiary Cardiac Centre**
Dr. Mahmoud Barbir - *Consultant Cardiologist, Royal Brompton and Harefield NHSFT; Hon Senior Lecturer Dept of Medicine, Imperial College*

16:40 – 17:05 **Working Together in Diabetic Foot Care for the vulnerable patient**
Professor Mike Edmonds - *Professor of Diabetic Foot Medicine and Consultant Physician, Kings College Hospital, London*

17 05 – 17:30 **EXTOD: Exploring the Barriers and Benefits of Physical Exercise for People with Type 1 Diabetes**
Dr. Parth Narendran - *Reader in Diabetes Medicine and Honorary Consultant, University of Birmingham*

17:30 – 17:50 **Diabetes Retinopathy – How to Reduce Progression and Treat Sight Threatening Disease**
Dr. Samantha Mann - *Consultant Ophthalmologist, GSTT NHSFT*

17:50- 18:10 **Inpatient Medicine Safety and Quality Improvement**
Philip Newland-Jones - *Consultant Pharmacist, Diabetes and Endocrinology, University Hospitals Southampton NHSFT*

18:10 -18:30 **Panel Discussion & Close**

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About our event chairs

Professor Michael D Feher

Michael D Feher is Consultant Physician in Diabetes and Clinical Pharmacology at the Chelsea & Westminster Hospital, London, and Visiting Professor within Clinical Informatics and Health Outcomes Research Group, Nuffield Department of Primary Care Health Sciences, University of Oxford.

He has had extensive clinical experience in diabetes, lipids and hypertension, combining clinical pharmacology, pharmaco-epidemiology and laboratory-based research with diabetes clinical care and teaching. Publications include eight books in diabetes and cardiovascular medicine.

He is independent diabetes assessor to London Metropolitan/Home County Police. Committee membership of Heart UK, European Medicines Agency (EASD Diabetes representative and special advisory panel) and Secretary State for Transport Honorary Medical Advisory Panel (DVLA) panel for Driving and Diabetes. He is on the Editorial Board of the British J of Diabetes.

Dr. David Hopkins

Dr Hopkins is a Consultant Physician and Diabetologist. He is Clinical Director for King's diabetes service and Joint Clinical Academic Lead across King's Health Partners. Dr Hopkins leads one of the largest specialist diabetes teams in the UK. He conducts a wide range of specialist diabetes clinics including insulin pump management, diabetic nephropathy, autonomic neuropathy and gastrointestinal complications of diabetes. He qualified in medicine from Liverpool University and subsequently, trained in diabetes, endocrinology and internal medicine in Liverpool (1987-1995) and at King's (1995-1999) where he was a clinical academic group lead in 2014. Dr Hopkins was first appointed as a consultant at Central Middlesex Hospital in 1999 before returning to King's as a consultant in 2004. He became clinical director of the service in 2010 and clinical academic group lead in 2014. Dr Hopkins has broad research interests include management of hypoglycaemia, outcomes of structured patient education in type 1 diabetes and early detection of coronary artery disease in type 2 diabetes.

He has national roles as a member of the Diabetes UK Council of Health Professionals and of the DAFNE executive.

He acts as audit and quality assurance lead for the national DAFNE structured education programme.

SANOFI

Prescribing Information: Lantus® (insulin glargine) 100 units/ml solution for injection

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. *Elderly population (≥65 years old), patients with renal or hepatic impairment:* Insulin requirements may be diminished. *Children (<2 years of age)*: No data are available.

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. 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. 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:* 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. *Intercurrent illness:* requires intensified metabolic monitoring. *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 a reusable pen (JuniorSTAR which delivers Lantus in 0.5 unit dose increments and Autopen 24, AllStar and AllStar PRO which all deliver Lantus in 1 unit dose increments). 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 (≥1/10):* Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. *Common (≥1/100 to <1/10):* Lipohypertrophy, injection site reactions. *Uncommon (≥1/1,000 to <1/100):* Lipoatrophy. *Rare (≥1/10,000 to <1/1,000):* Allergic reactions, visual impairment, retinopathy and oedema. *Very rare (<1/10,000):* Dysgeusia, myalgia. Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. *Not known:* Cutaneous amyloidosis. **Please consult SmPC for full details of the adverse reactions.**

NHS list price: 1 x 10ml Lantus vial: £27.92; 5 x 3ml Lantus cartridge: £37.77; 5 x 3ml Lantus SoloStar: £37.77. **Legal category:** POM. **Marketing Authorisation (MA) holder**: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. **MA Numbers:** Vial : EU/1/00/134/012, Cartridge: EU/1/00/134/006, SoloStar: EU/1/00/134/033. **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 2020.

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

SANOFI

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:** 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 lactation:* 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.
UK List price: Toujeo SoloStar 3 x 1.5ml pens: £32.14, Toujeo DoubleStar 3 x 3ml pens: £64.27. **Legal Category:** POM. **Marketing Authorisation Number**: SoloStar 3 Pen pack: EU/1/00/133/034, DoubleStar 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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SANOFI

Prescribing Information: Suliqua® ▼ (insulin glargine 100 units/ml and lixisentatide)

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

Presentations: ***Suliqua 100 units/ml + 50 microgram/ml solution for injection in a pre-filled pen:*** Each containing 300 units of insulin glargine and 150µg lixisenatide in 3 ml solution. ***Suliqua 100 units/ml + 33 microgram/ml solution for injection in a pre-filled pen:*** Each containing 300 units of insulin glargine and 100µg lixisenatide in 3 ml solution.

Indication: Suliqua is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus, to improve glycaemic control as an adjunct to diet and exercise
in addition to metformin with or without SGLT-2 inhibitors.

Dosage and administration: Suliqua is to be injected subcutaneously in the abdomen, deltoid, or thigh. The injection sites should be rotated within the same region from one injection to the next to reduce the risk of lipodystrophy and cutaneous amyloidosis. Patients should be instructed to always use a new needle. Suliqua must not be drawn from the cartridge of the pre filled pen into a syringe to avoid dosing errors and potential overdose. Therapy with basal insulin or glucagon-like peptide-1 (GLP-1) receptor agonist or oral glucose lowering medicinal product other than metformin and SGLT-2 inhibitors should be discontinued prior to initiation of Suliqua. ***Suliqua 100 units/ml+50 µg/ml solution for injection in a pre-filled pen (10-40 pen):*** delivers dose steps from 10-40 units of insulin glargine in combination with 5-20µg lixisenatide. ***Suliqua 100 units/ml+ 33 µg/ml solution for injection in a pre-filled pen (30-60 pen):*** delivers dose steps from 30-60 units of insulin glargine in combination with 10-20µg lixisenatide. ***Starting dose:*** The starting dose of Suliqua is based on previous anti-diabetic treatment, and in order not to exceed the recommended lixisenatide starting dose of 10µg. ***Oral anti-diabetic treatment GLP-1 receptor agonist (insulin-naïve) patients:*** 10 dose steps (Suliqua 10-40 pen). ***Patients who have previously received ≥20<30 units insulin glargine (100 units/ml):*** 20 dose steps (Suliqua 10-40 pen). P***atients who have previously received ≥30≤60 units insulin glargine (100 units/ml):*** 30 dose steps (Suliqua 30-60 pen). ***Patients who previously received twice daily basal insulin or insulin glargine (300 units/ml):*** total daily dose previously used should be reduced by 20% to choose the Suliqua starting dose. Suliqua is to be dosed in accordance with the individual patient's need for insulin. It is recommended to optimise glycaemic control via dose adjustment based on fasting plasma glucose. Close glucose monitoring is recommended during the transfer and in the following weeks. Max. daily dose 60 units insulin glargine and 20µg lixisenatide corresponding to 60 dose steps. Suliqua should be injected once a day within 1 hour prior to a meal. It is preferable that the prandial injection is performed before the same meal every day. Patients adjusting the amount or timing of dosing should only do so under medical supervision with appropriate glucose monitoring. ***Elderly (≥65 years old):*** Dose should be adjusted on an individual basis, based on glucose monitoring. No dose adjustment is required for lixisenatide. Data is limited in patients ≥75 years of age. ***Severe renal impairment (creatinine clearance less than 30 ml/min) and end-stage renal disease:*** Suliqua is not recommended. ***Mild to moderate renal impairment; Hepatic impairment:*** No dose adjustment is required for lixisenatide. Insulin requirements may be diminished due to reduced insulin metabolism. Frequent glucose monitoring and dose adjustment may be necessary. ***Paediatric population:*** No data available.

Contraindications: Hypersensitivity to the active substances or to any of the excipients.

Warnings and precautions: ***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. Suliqua should not be used in patients with type 1 diabetes mellitus or for the 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:*** Hypoglycaemia was the most frequently reported observed adverse reaction during treatment with Suliqua. Hypoglycaemia may occur if the dose of Suliqua is higher than required. A number of factors may increase susceptibility to hypoglycaemia. These would require particularly close monitoring and may necessitate dose adjustment. ***Acute pancreatitis:*** Use of glucagon-like peptide-1 (GLP-1) receptor agonists has been associated with a risk of developing acute pancreatitis. There have been few reported events of acute pancreatitis with lixisenatide although a causal relationship has not been established. Patients should be informed of the characteristic symptoms of acute pancreatitis: persistent, severe abdominal pain. If pancreatitis is suspected, Suliqua should be discontinued; if acute pancreatitis is confirmed, lixisenatide should not be restarted. Caution should be exercised in patients with a history of pancreatitis. ***Severe gastrointestinal disease:*** Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. Suliqua has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and therefore, the use of Suliqua is not recommended in these patients. Concomitant medicinal products: The delay of gastric emptying with lixisenatide may reduce the rate of absorption of orally administered medicinal products. Suliqua should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption, require careful clinical monitoring or have a narrow therapeutic ratio. ***Dehydration:*** Patients treated with Suliqua should be advised of the potential risk of dehydration in relation to gastrointestinal adverse reactions and take precautions to avoid fluid depletion. ***Antibody formation:*** Administration of Suliqua may cause formation of antibodies against insulin glargine and/or lixisenatide. In rare cases, the presence of such antibodies may necessitate adjustment of the Suliqua dose in order to correct a tendency for hyperglycaemia or hypoglycaemia. ***Avoidance of medication errors:*** Patients must be instructed to always check the pen label before each injection to avoid accidental mix-ups between the two different strengths of Suliqua and mix-ups with other injectable diabetes medicinal products. ***Excipients:*** This medicinal product contains <1 mmol (23 mg) sodium per dose, thus is essentially 'sodium-free'. It also contains metacresol, which may cause allergic reactions. ***Interactions:*** Patients receiving medicinal products of either a narrow therapeutic ratio or medicinal products that require careful clinical monitoring should be followed closely, especially at the time of initiation of lixisenatide treatment. These medicinal products should be taken in a standardised way in relation to lixisenatide. If such medicinal products are to be administered with food, patients should be advised to, if possible, take them with a meal when lixisenatide is not administered. For oral medicinal products that are particularly dependent on threshold concentrations for efficacy, such as antibiotics, and gastro-resistant formulations containing substances sensitive to stomach degradation, patients should be advised to take those medicinal products at least 1 hour before or 4 hours after lixisenatide injection. ***Fertility, pregnancy and lactation:*** Suliqua is not recommended in women of childbearing potential not using contraception. No clinical data on exposed pregnancies from controlled clinical studies. Although >1000 pregnancy outcomes with insulin glargine indicate no specific adverse effects on pregnancy, there are no adequate data from the use of lixisenatide in pregnant women. Studies with lixisenatide in animals have shown reproductive toxicity. Suliqua should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, treatment with Suliqua should be discontinued. It is unknown whether insulin glargine or lixisenatide is excreted in human milk, thus should not be used during breastfeeding. Animal studies with lixisenatide or insulin glargine do not indicate direct harmful effects with respect to fertility.

Adverse reactions: ***Very common:*** Hypoglycaemia. ***Common:*** Dizziness, Nausea, Diarrhoea, Vomiting, Injection Site Reactions. ***Not known:*** Cutaneous amyloidosis, lipodystrophy.

Legal classification: POM. **List price:** Suliqua 100 units/ml + 50µg/ml solution for injection in a pre-filled pen (10-40 pen) x3 pack: £67.50; Suliqua 100 units/ml + 33µg/ml solution for injection in a pre-filled pen (30-60 pen) x3 pack: £48.60. **Marketing authorisation holder:** Sanofi-aventis groupe, 54, rue La Boétie, 75008 Paris, France. **Marketing authorisation numbers:** EU/1/16/1157/001-006. **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 2020. MAT-GB-2002422 (v1.0)

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Adverse events should also be reported to Sanofi Tel: 0800 090 2314.
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▼This medicine is subject to additional monitoring. Healthcare professionals are strongly encouraged to report any suspected adverse reactions. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Sanofi tel: 0800 0902314. Alternatively, send via email to uk-drugsafety@sanofi.com

Prescribing Information: Praluent®▼ (alirocumab) solution for injection in pre filled pen

Please refer to the Praluent Summary of Product Characteristics (SPC) for full prescribing details.
Presentations: Praluent 75mg or 150mg solution for injection, in a pre-filled pen or pre-filled syringe, contains 75mg alirocumab in 1ml solution or 150mg alirocumab in 1ml solution, respectively.
Indications: Praluent is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. Praluent is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or, alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
Dosage and Administration: Secondary causes of hyperlipidaemia or mixed dyslipidaemia (e.g., nephrotic syndrome, hypothyroidism) should be excluded prior to initiation of alirocumab. Alirocumab is injected as a subcutaneous injection into the thigh, abdomen or upper arm. It is recommended to rotate the injection site with each injection. Alirocumab should not be injected into areas of active skin disease or injury such as sunburns, skin rashes, inflammation, or skin infections. Alirocumab must not be co-administered with other injectable medicinal products at the same injection site. The patient may either self-inject Praluent, or a caregiver may administer Alirocumab, after guidance has been provided by a healthcare professional on proper subcutaneous injection technique. The solution should be allowed to warm to room temperature for 30 to 40 minutes prior to use. The usual starting dose is 75mg, once every 2 weeks. Patients requiring larger LDL-C reduction (>60%) may be started on 150mg once every 2 weeks or 300mg once every 4 weeks. A dose of 300mg should be given as two 150mg injections consecutively at two different injection sites. If a dose is missed, the patient should administer the injection as soon as possible and thereafter resume treatment on the original schedule. Lipid levels can be assessed 4 to 8 weeks after treatment initiation or titration, and dose adjusted accordingly (up-titration or down-titration). If additional LDL-C reduction is needed in patients treated with 75mg once every 2 weeks or 300mg once every 4 weeks (monthly), the dosage may be adjusted to the maximum dosage of 150mg once every 2 weeks.
Special populations: *Elderly:* No dose adjustment needed. *Hepatic impairment:* No dose adjustment is needed for patients with mild or moderate hepatic impairment. Alirocumab should be used with caution in patients with severe hepatic impairment (Child-Pugh C). *Renal impairment:* No dose adjustment is needed for patients with mild or moderate renal impairment. Alirocumab should be used with caution in patients with severe renal impairment. *Body weight:* No dose adjustment needed in patients based on weight. *Children and adolescents (<18 years):* No data are available.
Contraindications: Hypersensitivity to the active substance or to any of the 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. *Allergic reactions:* General allergic reactions, including pruritus, as well as rare and sometimes serious allergic reactions such as hypersensitivity, nummular eczema, urticaria, and hypersensitivity vasculitis have been reported in clinical studies. Angioedema has been reported. If signs or symptoms of serious allergic reactions occur, treatment with alirocumab must be discontinued and appropriate symptomatic treatment initiated. *Interactions:* no pharmacokinetic effects of alirocumab on other medicinal products and no effect on cytochrome P450 enzymes are anticipated. Statins and other lipid lowering therapies can increase clearance of Praluent; however, LDL-C reduction was maintained on two weekly alirocumab administrations. *Pregnancy, Lactation and Fertility:* There are no data from the use of Praluent in pregnant women and is expected to cross the placental barrier, thus use of Praluent is not recommended during pregnancy unless the clinical condition of the patient warrants it. Praluent is not recommended in breastfeeding women when colostrum is produced; for the rest of the breast-feeding period, a decision should be made whether to discontinue nursing or to discontinue Praluent. There are no data on adverse effects on fertility in humans.
Adverse Reactions: *Common (≥ 1/100 to < 1/10):* local injection site reactions (including erythema/redness, itching, swelling, pain/tenderness), upper respiratory tract signs and symptoms (oropharyngeal pain, rhinorrhea, sneezing), and pruritus. *Rare (≥1/10,000 to <1/1,000):* Hypersensitivity, hypersensitivity vasculitis, urticaria and eczema nummular. *Not known:* Flu-like illness, angioedema. **Please refer to the SPC for full details on adverse reactions. Special precautions for storage:** Store in a refrigerator (2°C to 8°C). Keep the pen in the outer carton in order to protect from light.
Legal Category: POM. **List price:** 1x 75mg or 150mg pre-filled pen: £168. 2x 75mg or 150mg pre-filled pen: £336. **Marketing Authorisation (MA) Numbers:** 1x 75mg: EU/1/15/1031/001, 2x 75mg: EU/1/15/1031/002, 1x 150mg: EU/1/15/1031/007, 2x 150mg: EU/1/15/1031/008. **MA Holder:** Sanofi-Aventis groupe, 54 rue La Boétie, F - 75008 Paris, France. **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: June 2020.**

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902314. Alternatively, send via email to UK-drugsafety@sanofi.com

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