Prescribing Protocol SESLHDPR/638
Safe Use of High Concentration Insulin Glargine 300 units/mL (Toujeo®)

NSW GOVERNMENT Health
South Eastern Sydney Local Health District

High Concentration Insulin Glargine 300 units/mL (TOUJEO®) IS A HIGH RISK MEDICINE

USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY

Areas where applicable	SESLHD
Areas where not applicable	Paediatric Areas
Authorised Prescribers:	**Initiation is restricted to Endocrine consult only** All Medical Officers and Nurse Practitioners may prescribe for patients admitted to hospital using this product.
Indication for use	Treatment of Diabetes Mellitus in Adults
Important Safety Considerations	Insulin glargine 300 units/mL (Toujeo®) is **three times more concentrated** than standard insulin products. That is, the same volume of Toujeo® will have three times the effect on blood glucose levels as standard insulin. The lack of staff familiarity with the product can potentially result in three-fold dosing errors when patients using this product are admitted to hospital. Toujeo® is available as a disposable injector pen. Whenever possible, patients should self-administer their Toujeo® (high concentration insulin) from the pen device using a standard pen needle. They must be able to manage the pen device and dispose of their pen needle safely. An independent double check is required for every administration in accordance with NSW Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities. If the patient is unable to use the Toujeo® pen device, a nurse must only administer Toujeo® using the pen device if a safety needle is used. **A syringe should never be used to withdraw insulin from the pen device due to the high potential for dosing errors.** An independent double check is required for every administration in accordance with NSW Health Policy.
Contraindications	Toujeo® must not be used in patients hypersensitive to insulin glargine or any of the excipients.

Precautions	**Hypoglycaemia:** • As with all insulin, especially if recurrent, prolonged or severe hypoglycaemic episodes may be life threatening. Particular caution should be exercised, and intensified blood glucose monitoring is advisable in patients in whom hypoglycaemic episodes might be of particular clinical relevance, such as in patients, With recurrent hypoglycaemia; • Who are elderly, have low body weight or who have impaired renal function **Switching between Toujeo® 300units/mL and insulin glargine 100 units/mL** Toujeo® 300 units/mL and Insulin glargine 100 units/mL are not bioequivalent and are not directly interchangeable. Switching between Toujeo® 300 units/mL and insulin glargine 100 units/mL (Lantus®) may require a reduction in insulin glargine dose by 10 to 15%. This switch should only be done under close medical supervision and under the guidance of an endocrinologist. **Switching between other insulins and Toujeo®** Switching a patient between another type of insulin (not insulin glargine) and Toujeo® should only be done under the close guidance of an endocrinologist. **Medication error prevention** Insulin labels must always be checked carefully before each injection to avoid medication errors between Toujeo® and other insulins. Patients must be instructed to never reuse a needle. A new sterile needle must be attached before each injection. **Use in pregnancy** (Category B3) Safety and effectiveness of Toujeo® have not been established in pregnancy. **Use in lactation.** Lactating women may require adjustments in insulin dose and diet. **Use in the elderly** In the elderly, deterioration of renal function may lead to decreased insulin requirements. Careful glucose monitoring and dose adjustments of insulin, including Toujeo® may be necessary in the elderly patients. **Paediatric use** Safety and effectiveness of Toujeo® have not been established in paediatric patients. **Renal impairment** In patients with renal impairment, insulin requirements may be diminished due to reduced insulin excretion. **Hepatic impairment** In patients with severe hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis.

Important Drug Interactions	**Substances that may enhance the blood glucose lowering effect and increase susceptibility to hypoglycaemia.** Oral antidiabetic agents, angiotensin converting enzyme (ACE) inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase (MAO) inhibitors, pentoxifylline, propoxyphene, salicylates and sulfonamide antibiotics. **Substances that may reduce the blood glucose lowering effect of insulin.** Corticosteroids, danazol, diazoxide, diuretics, glucagon, isoniazid, oral contraceptives, phenothiazine derivatives, somatotrophin, sympathomimetic agents (e.g. adrenaline (epinephrine), salbutamol.
Place in Therapy	Toujeo® may be used by some people with diabetes, for example in order to decrease the daily injection volume in those with severe insulin resistance requiring high doses of insulin.
Dosage **(Include dosage adjustment for specific patient groups)**	Toujeo® (insulin glargine) 300 units/mL is available as a disposable injector pen and is three times more concentrated that standard insulin products. The lack of staff familiarity with the product can result in three-fold dosing errors when these patients are admitted to hospital. Toujeo® is used once daily and requires individualised dosing and dose adjustment. See “Precautions” section above for information on switching from insulin glargine 100units/mL and other insulins. **Patients with type 1 diabetes mellitus.** In type 1 diabetes mellitus, Toujeo® must be combined with short/rapid acting insulin to cover mealtime insulin requirements. **Patients with type 2 diabetes mellitus.** In patients with type 2 diabetes mellitus, Toujeo® can be given together with orally active antidiabetic medications. **Dosing in renal impairment** In patients with type 2 diabetes who are older than 70 or have eGFR < 30 mL/min lower doses may be required. **General** With Toujeo®, a dose of 1 to 80 units per injection, in steps of one (1) unit, can be injected. The dose counter shows the number of units that are to be injected. The Toujeo SoloStar® prefilled pen has been specifically designed for Toujeo®, therefore no dose recalculation is required. The desired blood glucose levels as well as doses and timing of antidiabetic medication must be determined and adjusted individually.
Duration of therapy	As clinically indicated.
Prescribing Requirements	Ensure medication orders for high concentration insulin products include the full brand name. Ensure that the insulin dose is clear to all staff involved in the handling of the high concentration insulin. If the treating team has enquiries or concerns about prescribing Toujeo®, the Endocrinology Team should be contacted.

Administration Instructions	Toujeo® is a basal insulin for once daily subcutaneous administration at any time of the day, preferable at the same time every day. Before first use. The pen must be stored at room temperature at least one hour before use. After use it should be kept at room temperature (below 30º C) and discarded after 28 days. Label the syringe clearly with the date of first use. Inspect the cartridge prior to administration; it must only be used if the solution is clear, colourless, with no solid particles visible, and if it is of water-like consistency. Whenever possible, patients should self-administer their high concentration insulin under supervision, using a standard pen needle. If it is necessary for staff to administer a dose of high concentration insulin then a safety pen needle must be used. Refer to BD AutoShield Duo™ Safety Pen Needle Instructions for Use for specific instructions on use of safety pen needles. Refer to 'Safe Administration of Medication Pen Devices' for more detail. **Toujeo® must not be drawn from the cartridge of the prefilled pen into a syringe.** Empty pens must never be reused and must be properly discarded. Toujeo® must not be used in insulin infusion pumps. **Insulin glargine 100 units/mL and Toujeo® are not interchangeable.** Always administer the correct brand and strength as prescribed. **Do not mix or dilute Toujeo®.** Toujeo® must not be mixed with any other insulin products. Mixing changes the time/action profile of Toujeo® and causes precipitation. Toujeo® must not be diluted. Diluting changes the time/action profile of Toujeo®.
Monitoring Requirements	Blood glucose monitoring and blood ketone monitoring should be performed as clinically indicated.
Management of complications	Refer to local business rules for management of hypo- and hyperglycaemia.

Storage requirements	**Unopened/not in use prefilled pen** Toujeo® must be stored between +2º C and +8º C (in a refrigerator) and protected from light. Do not allow the insulin to freeze, discard if frozen. Do not put Toujeo® next to the freezer compartment or a freezer pack. **Opened/in use** Opened prefilled pen must be discarded after 28 days (4 weeks) from the first use. The open prefilled pen of Toujeo® should be kept away from direct heat and light, at room temperature (below 30ºC). Toujeo® should be supplied from pharmacy on an individual basis and the patient's medication chart clinically reviewed by a pharmacist prior to supply. The pharmacy dispensing label should include a warning that it is a high concentration insulin product. The product should be stored separately from standard insulin products. Any dispensed products that are no longer required should be removed from the clinical area at the earliest opportunity.
Additional Resources	• BD AutoShield Duo™ *Safety Pen Needle General Recommendations* • Clinical Excellence Commission, *Safe Administration of Medication Pen Devices*, June 2019
Basis of Protocol/Guideline: (including sources of evidence, references)	MIMS, Toujeo® Insulin Glargine, 01 April 2021 NSW Health Safety Notice 007/19 High Concentration Insulin Products (Updated) June 2019 NSW Health Policy Directive PD2020_045 High-Risk Medicines Management Policy NSW Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities. BD AutoShield Duo™ Safety Pen Needle General recommendations
Groups consulted in development of this guideline	SESLHD – Diabetes CNC St George Hospital, Denise Craig SESLHD – Diabetes CNC Prince of Wales Hospital, Julie Gale SESLHD – Katie Hargreaves, QUM Lead Pharmacist SESLHD – Ann Poynten Staff Specialist Prince of Wales Hospital SESLHD – Anthony O'Sullivan, Head, Department of Endocrinology, St George Hospital

SAFE ADMINISTRATION OF MEDICATION PEN DEVICES

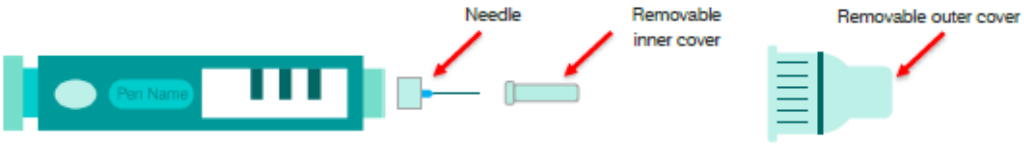
INFORMATION FOR HEALTH CARE PROVIDERS

Numerous injectable medications are now available as pen devices. Many of these are insulins and glucagon-like peptide-1 analogues, used for the treatment of diabetes. Wherever possible, patients should administer their own medication pen devices using a **standard pen needle** or **safety pen needle**. If it is necessary for staff to administer a pen device, a safety pen needle should be used for each dose.

There have been reports of patients and staff administering insulin using standard pen needles without removing the inner cover, mistaking them for safety pen needles. Patients received inadequate insulin, resulting in hyperglycaemia and other complications. It is easy to become accustomed to using safety pen needles and overlook when a standard pen needle may be in use. Staff and patients should be educated on the difference between needles and check which type they have, before each dose is administered.

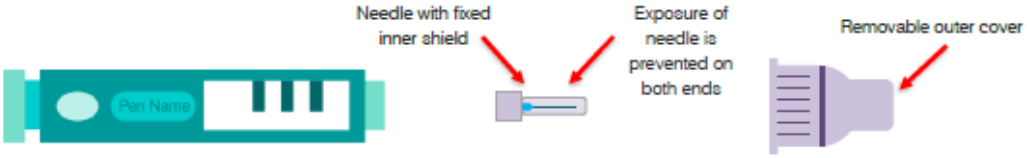
Standard Pen Needles

Standard pen needles will often have a needle covered by a removable inner cover and outer cover. BOTH the inner and outer covers must be removed before an injection.



Safety Pen Needles

Safety pen needles have a needle with a fixed inner shield and often have an outer cover. The outer cover is removed before an injection but the fixed inner shield stays on.

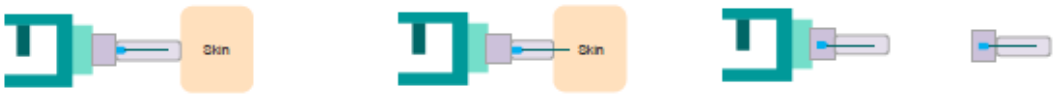


Using the Safety Pen Needle

The needle with fixed inner shield is placed against the skin.

The injection button is pressed and the needle extends out of the fixed inner shield, penetrating the skin and delivering the dose.

When the injection is completed, the needle *automatically retracts within the shield*. The needle is locked inside, preventing needlestick injury and can be safely removed from the pen.



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GOVERNANCE	
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