How to start Apidra® (insulin glulisine) in Type 2 Diabetes

Please review the full product data sheets available at www.medsafe.co.nz

When printing this PDF please include the reference and product mandatory sections.

This information is for Healthcare professional use only.

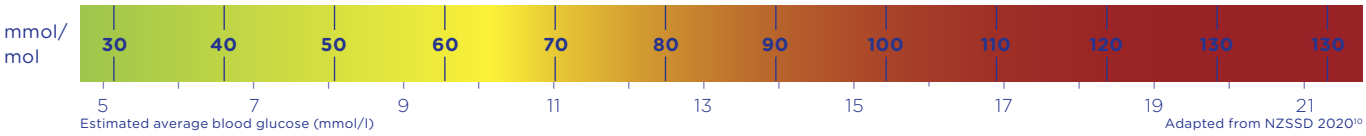
SANOFI

Before Starting Apidra®

- HbA1c persistently above individualised target (>3months).[1]

Recommended target for Type 2 Diabetes patients:
HbA1c 50-55 mmol/mol or as individually agreed.[1]

HbA1c an indicator of average blood glucose control



- Address other possible causes of hyperglycaemia[1] ☐
  - Lifestyle (e.g diet, exercise, excess weight) ☐
  - Lack of adherence with current medications ☐
  - Suboptimal use of Lantus® (Review further need for Lantus® titration to achieve FPG at target)[8] ☐
  - Suboptimal use of oral hypoglycaemic medications ☐
  - Other medications or medical conditions that can cause hyperglycaemia ☐
- Discuss barriers/concerns about adding another insulin with patient[1] ☐
- Arrange a Care Plan if necessary – explain role of other healthcare professionals in patient education and monitoring[1] ☐
- Conduct regular testing to determine patient's blood glucose profile pattern ☐
- Select Apidra® insulin device: ☐
  - Apidra® SoloSTAR® disposable pen & needles

OR

  - Apidra® AllStar Pro® pen & Apidra® 3mL cartridges & needles

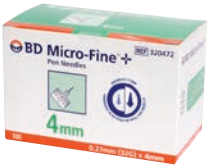
OR

  - Apidra® 10mL vial & syringes with attached needle

  - Apidra® SoloSTAR pens, cartridges and vials all display a mealtime icon

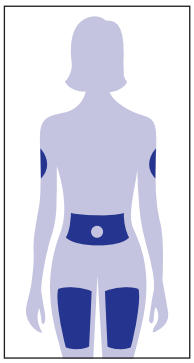
Remember to:

- Allow additional Apidra® units to cover the 2 unit safety test (priming) prior to each injection[2] ☐
- Provide Apidra® information books and blood glucose books, which are available from Sanofi to assist your patient starting Apidra®. Contact 0800 283 684 ☐
- Co-prescribe a 3 month supply of BD Micro Fine™+ needles (200 needles or 200 syringes with attached needle)[9] ☐

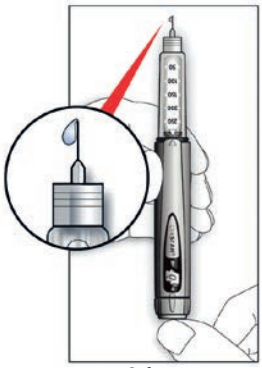


Advise your patient to:[2]

- Check that they have the right insulin, time and dose before injecting ☐
- Check that their Apidra® has not expired ☐
- Wash their hands thoroughly before starting each injection ☐
- Prime the needle: Perform a 2 unit safety test before each injection to ensure insulin is coming out of the needle ☐
- Inject Apidra ® at mealtimes as needed. Apidra® should be given by injection within 15 minutes before a meal or within 20 minutes after starting a meal. ☐
- Use a new needle for each Apidra® injection ☐
- Inject Apidra® at a 90° angle ☐
- Count to 10 before removing the needle from the injection site ☐
- Inject Apidra® into a different place every day. Sites for injection include abdomen, thighs and upper arms ☐
- Keep Apidra® SoloSTAR® disposable pen, the Apidra® cartridge or vial they are using at room temperature, not higher than 25°C, and protected from the light ☐
- Store unopened pre-filled pens, cartridges and vials in the fridge between 2°C and 8°C. Do not allow to freeze ☐
- Discard any remaining Apidra® 28 days after first use ☐



Recommended injection site usually the abdomen, other injection site options include thighs and upper arms



Safety test (priming)

Advise patients:[2]

- **Not** to confuse their insulins – Apidra® is clear, not cloudy. Apidra® is a rapid acting insulin ☐
- **Not** to use Apidra® if their pre-filled pen, vial or cartridge becomes cracked, cloudy or particles appear ☐
- **Not** to use Apidra® if the pre-filled pen, vial or cartridge has been frozen or exposed to excessive heat (25°C +) ☐
- **Not** to mix Apidra® with Lantus® and most other insulins (Apidra® can be mixed with NPH) ☐

Missed Dose:

1. **Advise patients that if they forget to take a dose of Apidra®, as with any insulin never take a double dose to make up for a missed dose as they will be at increased risk of hypoglycaemia.[2]**
2. **Advise patient to seek healthcare advice.[2]**

NPH (Neutral Protamine Hagedorn) : Isophane

Simple steps to achieving the right Apidra® (insulin glulisine) dose in Type 2 Diabetes patients needing a mealtime insulin added to their Lantus® regimen

Starting T2DM patients on Apidra®

Step 1:

Identify the 'main meal' – the meal which contributes the most to postprandial hyperglycaemia[3-5]

Step 2:

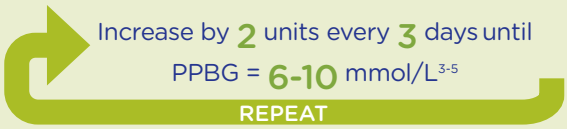
Commence 4 units of Apidra® with the 'main meal'[3,4,10]

Review sulphonylurea requirements when starting Apidra® at this meal

Step 3:

Choose a patient directed titration schedule

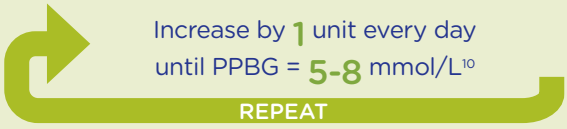
Schedule 1:



Adjust the Apidra® dose by 2 units every 3 days to achieve a 2 hour PPBG of 6-10 mmol/L, or as individually agreed[3-5]

OR

Schedule 2:



Adjust the Apidra dose by 1 unit every day to achieve a 2 hour PPBG of 5-8 mmol/L or as individually agreed[10]

Patients need to be aware that a significant reduction in the carbohydrate content of their meal will require a reduction in the dose of their meal time insulin.

Reduce the Apidra® dose and consider stopping sulphonylurea if hypoglycaemia occurs.

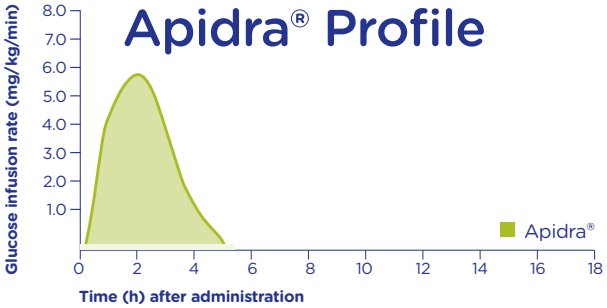
Step 4:

Review HbA1c at 3 months[1,4,5,8]

Step 5:

Review the need for Apidra® at other meal times if HbA1c > 55 mmol/mol, or above the target that has been individually agreed[3-6]

PPBG = Post Prandial Blood Glucose **T2DM** = Type 2 Diabetes Mellitus



Adapted from Becker et al 20087.[7]
Mean GIR in subjects with Type 1 diabetes after SC injection of 0.15 u/kg

References

Apidra®

1. New Zealand Primary Care Handbook 2012. Ministry of Health
2. Apidra® Consumer Medicine Information. October 2017
3. Diabetes Australia/RACGP Diabetes Management in General Practice.2016/2018
4. Nathan D, et al. Diabetes Care 2009; 32 (1): 193-203
5. Owens Dr, et al. Pract Diab Int 2009;26:70-77
6. Fulcher G, et al. AMJ 2010;3:808-813
7. Becker R. Clin.Pharmacokinet.2008;47:7-20
8. Melanie J. Davies et al. Diabetes Care 2018; 41: 2669-2701
9. New Zealand Pharmaceutical Schedule. April 2020
10. Harris SB, et al. Diabetes Care 2014;37:604–610
11. NZSSD resource from Department of Medical Illustration, Auckland City Hospital. https://www.nzssd.org.nz/hba1c Accessed 16/04/20120

Apidra® Abridged Data Sheet
Please review Full Data Sheet before prescribing – available at www.medsafe.govt .nz or from the sponsor.

Apidra® (insulin glulisine). **Indication:** Subcutaneous administration for type 1 and type 2 diabetes mellitus patients who require insulin for control of hyperglycaemia. **Contraindications:** Hypersensitivity to insulin glulisine or any excipient. **Precautions:** Hypoglycaemia; hepatic, renal and visual impairment; lipodystrophy and other injection site or immediate-type allergic reactions; patient instruction on intercurrent conditions, blood glucose monitoring, injection technique, checking insulin label if using reusable injection devices; not studied in children <4 years, pregnancy category B3, lactation; may be mixed with NPH human insulin, mixtures should not be administered intravenously. Interactions: Oral antidiabetic agents; cardiovascular, analgaesic, anti-inflammatory, neurological, antipsychotic agents (see full Data Sheet); antibiotics; corticosteroids, other hormonal therapies (see full Data Sheet); diuretics; protease inhibitors; sympathomimetic agents; lithium; alcohol; sympatholytics including ß-blockers; others, see full Data Sheet. **Adverse effects:** Hypoglycaemia; injection site reactions; others, see full Data Sheet. **Dosage and Administration:** Subcutaneous; abdominal, thigh or deltoid administration; blood glucose monitoring is recommended. Apidra® is equipotent to human insulin but with more rapid onset and shorter duration of action; should be injected within 15 minutes before or immediately after a meal. Initial dose should be determined individually, depending on desired blood glucose levels. Apidra® should normally be used in regimens that include a longer-acting or basal insulin. Apidra® can be mixed with NPH human insulin for subcutaneous administration. For secondary dose adjustments, renal, hepatic impairment: see full Data Sheet. **Presentations:** Apidra® (insulin glulisine injection) 100 U per mL (U 100) is available in packs of 10mL vials, 3mL cartridges and 3mL cartridges in SoloStar pre-filled pens. **Medicine Classification:** Prescription Medicine. Sponsor: Sanofi–Aventis New Zealand Limited trading as Sanofi, Level 8, 56 Cawley Street, Ellerslie, Auckland, New Zealand. Freephone 0800 283 684. **Apidra® is a Funded Medicine.**

Lantus®

Lantus® Abridged Data Sheet
Please review Full Data Sheet before prescribing – available at www.medsafe.govt .nz or from the sponsor.

Lantus® (insulin glargine). **Indication:** Once-daily subcutaneous administration for type 1 and type 2 diabetes mellitus patients who require insulin for control of hyperglycaemia. **Contraindications:** Hypersensitivity to insulin glargine or any excipient. **Precautions:** Hypoglycaemia, possibly with delayed recovery or altered warning symptoms; hepatic, renal and visual impairment; lipodystrophy and other injection site or immediate-type allergic reactions; antibody production; not studied in children <6 years, pregnancy category B3, lactation; not intended for i.v. use; not recommended for treatment of diabetic ketoacidosis; LANTUS® MUST NOT BE DILUTED OR MIXED WITH ANY OTHER INSULIN OR SOLUTION. Patient instruction on intercurrent conditions, blood glucose monitoring, injection technique recommended. **Interactions:** Oral antidiabetic agents; cardiovascular, analgesic, anti-inflammatory, neurological, antipsychotic agents, antibiotics, corticosteroids, other hormonal therapies, diuretics, protease inhibitors, sympathomimetic agents, lithium, alcohol, sympatholytics including ß-blockers, others. **Adverse effects**: Hypoglycaemia; injection site reactions; visual disturbances; others. **Dosage and Administration:** Subcutaneous, once daily; abdominal, thigh or deltoid administration; blood glucose monitoring is recommended. Lantus® is equipotent to human insulin. Initial dose should be determined individually, depending on desired blood glucose levels and doses and timing of any antidiabetic medication, including Lantus®. For changeover from once-daily NPH initial dose usually not changed; for changeover from twice-daily NPH to once-daily Lantus®, initial dose usually reduced by approximately 20% compared to total daily NPH dose; for initiation of type 2 patients, initial dose is usually approximately 10IU. For secondary dose adjustments, renal, hepatic impairment see full Data Sheet. **Medicine Classification:** Prescription Medicine. **Presentations:** Lantus® (insulin glargine injection) 100 U per mL is available in packs of 5x3mL cartridges, 5x3mL cartridges in SoloStar pre-filled pens and 10mL vials. Sponsor: Sanofi–Aventis New Zealand Limited trading as Sanofi, Level 8, 56 Cawley Street, Ellerslie, Auckland. Freephone 0800 283 684. **Lantus® is a Funded Medicine.**

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