Australian Commission on **Safety and Quality** in Health Care

Guidance
For clinicians

Discontinuation of insulin products: Strategies and safety considerations

What you need to know?

- The Therapeutic Goods Administration (TGA) has advised of changes to the supply of multiple insulin medicines.
- Alternative insulin products are available to replace many of the discontinued insulin medicines.
- People with diabetes requiring ongoing insulin therapy and using a product due to be discontinued will need to be switched to an appropriate alternative insulin preparation. The changeover requires careful management to ensure safety.
- Insulins are essential and potentially lifesaving medicines. However, they are high-risk medicines commonly involved in medication incidents leading to serious harm.
- Applying a safe prescribing checklist helps to mitigate risk when managing changes between insulin products, see **Highlight 1**.
- In some cases, the TGA may issue a Serious Scarcity Substitution Instrument (SSSI), which allows community pharmacists to substitute specific medicines, with the same active ingredient, without prior approval from the prescriber, under specific conditions. For example, SSSIs are in place for both Protaphane® InnoLet® and Ryzodeg® 70/30 FlexTouch®, allowing appropriate pharmacy substitution.

More information on safety considerations is included in this guidance to support health care professionals in transitioning people with diabetes to alternative insulin products.

Multiple insulin products are being discontinued globally by Novo Nordisk. In Australia, the discontinuations of the affected products will occur between late 2024 and late 2026. For most of the insulin products being discontinued, alternative products will remain available (Table 1). Up to date information on discontinued insulin products is available on the TGA website.

Safety considerations and risk mitigations should be considered to minimise the impact on people with diabetes, in responding to changes in availability of insulin products.

Purpose

This guidance has been developed by the Australian Commission on Safety and Quality in Health Care (the Commission) to assist clinicians provide safe and quality health care during the discontinuation of some insulin products in Australia. The guidance focuses on actions to mitigate risks associated with changing or switching between insulin products. It does not provide clinical guidance on insulin use.

Background

Insulins are high-risk medicines commonly used in the treatment and management of diabetes, including type 1, type 2, gestational and medication-induced diabetes. Insulin products differ in duration of onset and action, presentation and method of administration.

Table 1 Insulin products to be discontinued and alternative product(s).

Insulin product(s) to be discontinued	Planned discontinuation date (stock may be available after this date, until depleted)	Alternative product(s) to consider when changing or switching
Fiasp® (insulin aspart) FlexTouch® prefilled pen and vials	December 2024 (vials) March 2025 (FlexTouch®)	• Fiasp® (insulin aspart) Penfill® cartridge
Ryzodeg® (Insulin degludec + insulin aspart 70/ 30) FlexTouch® prefilled pen	February 2025	• Ryzodeg® (Insulin degludec + insulin aspart 70/30) Penfill® cartridge
Actrapid® (insulin neutral) Penfill® cartridge	December 2026	• Humulin® R (insulin neutral) cartridge • Actrapid® (insulin neutral) vial
Protaphane® (insulin isophane) InnoLet® prefilled pen and Penfill® cartridge*	February 2025 (Innolet®) December 2026 (Penfill®)	• Humulin® NPH (insulin isophane) cartridge • Protaphane® (insulin isophane) vial A long-acting insulin may also be considered as an alternative with careful monitoring. For further information about the discontinuation of Protaphane®, refer to the Discontinuation of Protaphane® InnoLet®: Strategies and safety considerations fact sheet.
Levemir® (insulin detemir) FlexPen® prefilled pen and Penfill® cartridge	December 2026	No like-for-like alternative available. Other long-acting insulins are available and may be deemed appropriate on a case-by-case basis.

*Note the Serious Scarcity Substitution Instrument (SSSI) for Protaphane® InnoLet® only allows community pharmacists to substitute Protaphane® InnoLet® insulin cartridges with Protaphane® Penfill® without prior approval from the prescriber, under specific conditions.

Safety considerations

To assist clinicians to provide safe and quality health care during the disruption to supply of insulin products, it is important to consider potential safety issues prior to changing insulin medicines.

Table 2 Potential safety issues to be considered prior to changing insulin products.

Consideration	Details
Appropriate prescribing of insulin	Follow the Safer prescribing checklist (Highlight 1)
Avoid misinterpretation	Always prescribe the dose in units rather than volume (mL).
Appropriate dosing	If there is clinical uncertainty about appropriate dosing when changing insulin products, specialist diabetes advice should be sought.
Monitoring	Careful observation is required when changing a person with diabetes to an alternative insulin. Blood glucose levels should be monitored regularly following a change in insulin.
Pharmacokinetic profile	Consider the pharmacokinetic profile when determining a new product and/or dosage regimen, noting that for alternative insulin products: • Duration of action and dosing intervals may differ • Onset of action and time to peak effect may vary.
Formulation (or dosage form)	Consider the suitability of the medicine's formulation for the person with diabetes, their family and carers. For insulin products not available in a disposable pen/device, use a cartridge loaded into a reusable pen device for subcutaneous administration. Safer use of cartridges and reusable pens is described in **Highlight 2.** Insulin vials should only be used in certain circumstances. For example, as outlined in the Clinical Excellence Commission: High-Risk Medicines Standard: Insulin. Most people have not had experience with using insulin syringes and vials and would need specific usage instruction on their use. In addition, an insulin pen device may be easier to use where there are dexterity issues, vision impairment and/or low levels of health and medicines literacy. Hospital-based prescribers should be familiar with local policies, procedures and guidelines regarding safe insulin prescribing and preferred insulin delivery devices.
Individual person factors	Examples of factors that can impact on the suitability and safety of alternative medicines include: • Manual dexterity in using pens and cartridges or vials and syringes • Visual impairment • Allergies or sensitivities to certain insulin alternatives.

	If there is clinical uncertainty about the individual factors that may compromise safety when changing insulin products, specialist diabetes advice should be sought.
Counselling	People with diabetes, their family or carers in the community or residential care, should be provided with appropriate education on the alternative insulin products. Changes to medicines present an opportunity to promote discussion and shared decision-making with people with diabetes and their family/carers. Some key factors to discuss when introducing an alternative, include: • Clear instructions and confirmation of alternative insulin product (for example, brand and medicine name) • Dosing instructions including device use instructions • Storage requirements • Cost of both the alternative insulin product and the device • Proper use, handling and method of administration of alternative insulin product and device
Transition of care	Ensure that insulin products and the devices used to deliver them are available and can be accessed when transitioning to different settings. For example, from hospital to community or metropolitan to rural/remote areas. Ensure any changes are communicated to all healthcare practitioners, and people involved in the care of the person with diabetes (e.g. their family and/or carer). Encourage the use of an up-to-date medicines list. When ceasing a medicine that is no longer available, record this information. Refer to Principles for safe and high-quality transitions of care for more information.
Electronic medication management (eMM) systems	Ensure the electronic prescribing system used reflects any product changes. The review should be overseen by the local medicines' governance committee, for instance, the Drug and Therapeutics Committee (or similar). The software should include mechanisms to prevent selection errors at the point of prescribing. However, prescribers should ensure all elements of the prescription, as per the Safer prescribing checklist, have been met.
Governance	Safer medication management is supported by local policies procedures and guidelines as well as overarching National Safety and Quality Primary and Community Healthcare Standards, and the Medication Safety Standard within the National Safety and Quality Health Service (NSQHS) Standards. Health service organisations should refer to the hospital pharmacy department and/or the local medicines governance committee for any sudden changes in availability that will impact insulin products for people with diabetes whilst they are in hospital.

Highlight 1: Safer prescribing checklist

Safe and quality use of medicines is supported by best practice prescribing principles. Applying a safe prescribing checklist helps to mitigate risk when managing changes in insulin medicines. To safely prescribe insulin medicines, always include the following on all prescriptions and medication orders (in accordance with state or territory legislative requirements):

- Active ingredient name
- Brand name*
- Strength or concentration with 'units' written in full (including correct proportions for pre-mixed and co-formulated insulins)
- Formulation, including delivery device
- Dose - always prescribe the dose in units and not volume (mL)
- Route
- Frequency and timing of dose
- Quantity for supply (as applicable for hospital discharge, residential aged care and in the community, or as per local policy, procedures and guidelines).

* Prescriptions should include both the insulin brand name and active ingredient name to support safer product identification and selection.

When prescribing, prescribers should also consider Pharmaceutical Benefits Scheme (PBS) restrictions and availability. The PBS website provides information on PBS reimbursement. Contact your hospital pharmacist or local community pharmacy to determine availability.

Risk mitigation strategies

- People who are newly diagnosed with diabetes who require insulin products should not be prescribed products that are to be discontinued. See **Table 1** Insulin products to be discontinued and alternative products.
- Proactively identify and review people with diabetes and are prescribed insulin products listed to be discontinued; support a switch to an alternative insulin prior to cessation of supply.
- Consider prescribing alternative insulin products with appropriate education, ensuring the person has access to the correct reusable insulin pen and is familiar with the selected insulin pen delivery system.
- Provide the required education, ideally including teach-back confirmation of understanding or refer to a credentialled diabetes educator for advice. See also Health Literacy - Supporting staff to meet health literacy needs fact sheet.
- Consider arrangements for further support for people where manual dexterity, vision or the ability to use the new device correctly would impact their safe use of insulin. A support person or family member may also need to be educated on using the alternative insulin.
- Review people with diabetes promptly following any changes; ensure they are using their new device appropriately; and monitor their blood glucose closely to ensure it is within target range.
- Awareness of product availability, including strength, concentration and formulation can assist with minimising safety risks to people with diabetes at the point of prescribing.
- For hospital settings: prescribers should be aware of what insulins (including mode of delivery) are available for initiation and continuation on the local/state-wide formulary.

If a clinically appropriate product is not available, contact your local Drug and Therapeutics Committee (or equivalent) or hospital pharmacy for advice on suitable alternatives.

Changing or switching insulin products

The discontinuation of multiple insulin products is resulting in an increased need to switch people with diabetes to other insulin preparations. The change has potential safety issues. **Table 2** details considerations to support safer prescribing and mitigate risk when changing an insulin product.

People with diabetes who use an insulin product that will be discontinued will need to be switched to an appropriate alternative insulin preparation. This may include switching those on a pre-filled pen device to the same insulin administered via a cartridge loaded in a reusable pen, or via syringe from an insulin vial or switching to a different insulin type.

Prior to making changes to an insulin regimen, prescribers are advised to use clinical judgement, established protocols and consider product availability and individual person factors in consultation with the person with diabetes and/or their family or carer.

Highlight 2: Safer use of cartridges and reusable pens[1]

Where possible, insulin cartridges may be individually dispensed and loaded into an appropriate delivery device at the point of dispensing and ensuring:

- the insulin cartridge is loaded into the reusable pen with the medicine name clearly visible through the 'window' of the delivery device
- engagement of the cartridge within the insulin pen when it is first loaded by priming appropriately
- the insulin cartridge is checked to confirm it contains the correct insulin and is within the expiry date before each administration (without removing it from the reusable pen)
- the pen is primed by expelling two units of insulin (repeat until insulin is visibly expelled from the needle) prior to dialling up each required dose so that an accurate dose is delivered. The device may need to be dialled up much further than 2 units to successfully engage the cartridge and prime the device.
- the reusable pens are not disposed of and retained for future use.

It is important that the person using the product is educated on how insulin cartridges are loaded into the delivery device; ideally at the point of dispensing and when administering the insulin.

[1]Adapted from Clinical Excellence Commission Safety Notice (SN:035/24): Discontinuation of multiple insulin products

Future considerations

Future considerations include strategies to address the risks from other insulin product discontinuations, particularly Levemir®. Levemir® has no comparable substitute and migration to a replacement will involve transition to a different intermediate-acting or long-acting insulin.

Useful resources

- Australian Commission on Safety and Quality in Health Care High risk medicine resources: Safer Prescribing, dispensing and use of insulins
- Consensus advice for health services and clinicians following the discontinuation of Novo Nordisk's InnoLet (Protaphane Insulin) Device. Australasian Diabetes in Pregnancy Society (ADIPS), Australian Diabetes Educators Association (ADEA), Australian Diabetes Society (ADS), Diabetes Australia (DA), Society of Obstetrics Medicine Australia and New Zealand (SOMANZ) and Royal Australian College of General Practitioners. [cited 2 Jan 2025]
- Changes to the supply of insulin products. Therapeutic Goods Administration (TGA). [cited 15 Jun 2026]
- About the changes to the supply of insulin products. Therapeutic Goods Administration (TGA). [cited 15 Jun 2026]
- Serious Scarcity Substitution Instruments (SSSIs). Therapeutic Goods Administration (TGA). [cited 17 Dec 2024]
- Insulin – High Risk Medicine Standard Clinical Excellence Commission [cited 23 Dec 2024]
- Diabetes Australia: Best Practice Guidelines [cited 20 Jan 2025]
- Diabetes Australia Diabetes quick guides: [cited 16 Dec 2024]
- Insulin fact sheet: National Diabetes Services Scheme [cited 17 Dec 2024]
- Australian Commission on Safety and Quality in Health Care guidance on conserving medicines within a focus on medicines shortages.
- Australian Commission on Safety and Quality in Health Care Principles for safe selection and storage of medicines.
- Australian Commission on Safety and Quality in Health Care National Safety and Quality Health Service (NSQHS) Medication Safety Standard
- Australian Department of Health and Aged Care Medication management in residential aged care facilities guiding principles
- Australian Department of Health and Aged Care Medication management in the community guiding principles
- Australian Commission on Safety and Quality in Health Care Principles for safe and high-quality transitions of care fact sheet
- Management of type 2 diabetes: A handbook for general practice. The Royal Australian College of General Practitioners (RACGP) [cited 17 Dec 2024]
- Clinical guidelines: Australian Diabetes Society (ADS) [cited 17 Dec 2024]
- Guidelines and Consensus Statements: Australia and New Zealand Society for Paediatric Endocrinology and Diabetes (ANZSPED) [cited 17 Dec 2024]
- Standards, position statements and other resources: Australian Diabetes Educators Association (ADEA) [cited 17 Dec 2024]
- Information for Health Care Providers: Australasian Diabetes in Pregnancy Society (ADIPS)
- The Pharmaceutical Benefits Scheme PBS website
- National Association of Diabetes Centres

State and Territory safety alerts and guidance

- NSW Health Safety Notice 035/24 - Discontinuation of multiple insulin products (16 Dec 2024; made obsolete 23 Sept 2025)
- NSW Health Safety Notice 023/25 – UPDATED: Discontinuation of multiple insulin products (23 Sept 2025)
- Queensland Health Fact Sheet – Discontinuation of Protaphane® InnoLet® and other insulin products (20 Dec 2024)

For more information

Please visit: TGA Medicine Shortage Reports Database or contact the Commission at medsafety@safetyandquality.gov.au or call 1800 304 056.