

Discontinuation of Protaphane[®] InnoLet[®] (human isophane insulin)

Key messages

- The Therapeutic Goods Administration (TGA) has advised on [changes to the supply of multiple insulin medicines](#) that will occur over the next two years.
- The TGA has advised that [Protaphane[®] InnoLet[®] 100 IU/mL injection multidose cartridge will discontinue](#) on 1 February 2025.
- People with diabetes requiring ongoing insulin therapy and currently using Protaphane[®] InnoLet[®] will need to be switched to an appropriate alternative insulin preparation. The changeover requires careful management to ensure patient safety.
- Applying a safe prescribing checklist helps to mitigate risk when managing changes between insulin products. See Guidance - [Discontinuation of insulin products: Strategies and safety considerations](#)
- The TGA has issued a [Serious Scarcity Substitution Instrument \(SSSI\)](#) for [Protaphane[®] InnoLet[®]](#) which allows community pharmacists to substitute Protaphane[®] InnoLet[®] insulin cartridges to Protaphane[®] Penfill[®] without prior approval from the prescriber, under specific conditions.

[Guidance - Discontinuation of insulin products: Strategies and safety considerations](#) provides more information for clinicians about transitioning people with diabetes to alternative insulin products.

Purpose

This fact sheet 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 Protaphane[®] InnoLet[®] insulin cartridges in Australia. The fact sheet focuses on actions to mitigate risks associated with changing or switching from Protaphane[®] InnoLet[®]. It does not provide any clinical guidance on Protaphane[®] InnoLet[®] use.

Insulin isophane

Human isophane insulin is an intermediate acting insulin with onset of action within 60 minutes and reaching a maximum effect within 4 to 12 hours. The duration of action is approximately 24 hours.

In Australia, insulin isophane is available in vials, prefilled insulin devices and Penfill[®]/pen cartridge formulations at 100 IU/mL marketed as Protaphane[®] (Novo Nordisk) and Humulin[®] NPH (Eli Lilly).

Protaphane[®] InnoLet[®] (human isophane insulin, 100 units/mL injection in a 3 mL pen device), will be discontinued in February 2025. The Protaphane[®] Penfill[®] 3 mL cartridges will be discontinued in December 2026.

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The InnoLet[®] delivery device was particularly helpful for people with a visual or physical impairment to be able to set and inject insulin doses. It is a pre-filled pen which delivers 1 to 50 units in increments of one unit. It comprises a pre-filled insulin reservoir and a dial with numbers and gives an audible click each time the dial is moved. The dial is turned to the number of units to be delivered, and the top of the device is pressed to administer the dose, after which the dial returns to zero.

The available options to replace the InnoLet[®] device are:

1. Novo Protaphane[®] in a Penfill[®] (cartridge) using a NovoPen[®] device
2. Eli Lilly Humulin[®] NPH Isophane in a pen cartridge using a HumaPen[®] device.

Insulin pens are made to fit specific brands of insulin. They are not interchangeable. The correct pen should be used for the brand of insulin pen cartridges prescribed.

The [Australian Diabetes Society \(ADS\)](#), [Australasian Diabetes in Pregnancy Society \(ADIPS\)](#), [Australian Diabetes Educators Association \(ADEA\)](#), [Diabetes Australia \(DA\)](#), [Society of Obstetric Medicine of Australia and New Zealand \(SOMANZ\)](#), and the [Royal Australian College of General Practitioners \(RACGP\)](#) – provide [consensus advice for health services and clinicians](#) in managing hyperglycaemia and diabetes following the discontinuation of Protaphane[®] InnoLet[®] (human isophane insulin). This includes clinical advice regarding potential use of alternative insulins that are not equivalent to insulin isophane.

Refer to [Guidance - Discontinuation of insulin products: Strategies and safety considerations](#) for more information on changing or switching insulin products.

Table 1: Protaphane[®] products to be discontinued, and appropriate available alternatives.

Insulin product to be discontinued	Planned discontinuation date (stock may be available after this date, until depleted)	Available alternative(s)
Protaphane [®] (insulin isophane) InnoLet [®] prefilled pen	February 2025	<ul style="list-style-type: none"> • Humulin[®] NPH (insulin isophane) cartridge • Protaphane[®] (insulin isophane) vial
Protaphane [®] (insulin isophane) Penfill [®] cartridge	December 2026	

Safety considerations

Protaphane[®] InnoLet[®] is relatively easy to use. Alternative preparations require higher levels of medicines literacy, manual dexterity and healthy vision. Some people with diabetes may require additional assistance to safely change to an alternative insulin, such as:

- Women with gestational diabetes, particularly those with low health literacy and language barriers which may make more complex devices harder to use
- Pregnant women with type 2 diabetes using InnoLet[®] devices
- People with limited dexterity or poor vision or who are older, may not be able to load cartridges as effectively or set the dial for the correct dose to be given
- People with diabetes who are also prescribed corticosteroids
- People with diabetes in hospital receiving enteral feeding or parenteral nutrition

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- Staff and carers responsible for delivering insulin therapy. There is added complexity of loading and correctly priming a cartridge device and a potential increase in time taken to give the injection
- People treated with Protaphane InnoLet® and another type of insulin because the InnoLet® device is easier to differentiate from other insulins. Changing to a different insulin may potentially increase the risk of administering the incorrect insulin.

Refer to [Guidance - Discontinuation of insulin products: Strategies and safety considerations](#).

Risk mitigation strategies

- Protaphane® InnoLet® should not be prescribed for people who are newly diagnosed with diabetes.
- Proactively identify and review people with diabetes who are prescribed Protaphane® InnoLet® to support a switch to an alternative insulin prior to the discontinuation date.
- Consider prescribing alternatives such as Protaphane® Penfill® or Humulin® NPH cartridges with appropriate education.
- Ensure the person has access to the correct reusable insulin pen and is familiar with the selected insulin pen delivery system.
- Avoid switching to Protaphane® Penfill® if the person with diabetes is likely to require this past December 2026.
- Provide the required education, ideally via the teach-back method of understanding or refer to a credentialed diabetes educator for advice. See [Health Literacy - Supporting staff to meet health literacy needs fact sheet](#).
- Consider arrangements for further support for people with diabetes 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 insulin product changes to ensure they are using their new device appropriately; and monitor closely to ensure blood glucose levels are within target range.

Useful resources

- [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 January 2025]
- [Upcoming changes to supply of some insulin products](#). Therapeutic Goods Administration (TGA). [cited 16 December 2024]
- [About the discontinuation of Protaphane InnoLet insulin cartridges](#). Therapeutic Goods Administration (TGA). [cited 16 December 2024]
- [Discontinuation of Protaphane InnoLet insulin cartridges and approval of a substitute](#). Therapeutic Goods Administration (TGA). [cited 16 December 2024]
- Australian Commission on Safety and Quality in Health Care [Guidance - Discontinuation of insulin products: Strategies and safety considerations](#)
- Australian Commission on Safety and Quality in Health Care [Guidance - Important changes for people who use insulin products fact sheet](#)
- Australian Commission on Safety and Quality in Health Care [Health Literacy - Supporting staff to meet health literacy needs fact sheet](#)

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- NSW Health Safety Notice 035/24 - [Discontinuation of multiple insulin products](#) (16 December 2024)
- Queensland Health [Fact Sheet – Discontinuation of Protaphane® InnoLet® and other insulin products](#) (20 December 2024)

For more information, visit [TGA Medicine Shortage Reports Database](#) or contact the Commission at medsafety@safetyandquality.gov.au or call 1800 304 056.

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