

Fact sheet

Discontinuation of Protaphane® InnoLet® and other insulin products

Purpose

The purpose of this fact sheet is to alert clinicians in community settings who prescribe, dispense or provide education regarding insulin administration, of the imminent discontinuation of the Protaphane InnoLet® insulin device as of February 2025.

Situation

Multiple insulin products are being discontinued by Novo Nordisk from the global market with stock of the affected products to be depleted over the next 2 years. For most of the insulin products being discontinued, alternative presentations will continue to be available in Australia.

Background

The decision by pharmaceutical company Novo Nordisk to discontinue multiple products remains, despite significant national advocacy from several peak diabetes organisations in Australia between September to November 2024.

The discontinuations and changes to administration devices are staggered and outlined in Attachment 1. In some cases, although one presentation of a product is discontinued, the product will remain available in a different presentation. For example, the Protaphane® InnoLet® will be replaced by Protaphane® PenFill® and Protaphane® vial. This is part of a global strategy and is not related to product safety, quality or effectiveness.

Protaphane® contains isophane insulin which is an intermediate acting insulin commonly used to treat steroid induced hyperglycaemia and increased fasting blood glucose levels in women with gestational diabetes mellitus.

The Protaphane® InnoLet® device will become unavailable in Australia from February 2025 with Protaphane® Penfill® cartridges being an alternative replacement. To minimise the impact on women, it is recommended all services review their workflows and education material.

Assessment

- Patients currently prescribed Protaphane® using an InnoLet® (pre-filled) device will need to be switched to Protaphane® Penfill® cartridges for administration (cartridge loaded into a reusable pen) if they are to continue beyond February 2025.
- The Therapeutic Goods Administration (TGA) has released a web statement and has made a Serious Scarcity Substitution Instrument (SSSI) to assist in managing the

discontinuation of Protaphane® InnoLet® from 1 February 2025. The [Therapeutic Goods \(Serious Scarcity and Substitutable Medicine\) \(Insulin Isophane Human\) Instrument 2024](#) has been registered and is now in force until 28 February 2026.

- Refer to Attachment 1 for a list of the insulin products being discontinued and the available alternatives. Some product alternatives will only be available temporarily. This includes Protaphane® Penfill® cartridge, the recommended alternative to Protaphane® InnoLet®, which will be discontinued in December 2026.

Recommendations

For women commencing isophane insulin who are early in pregnancy and will require it beyond February 2025, consider initiating a refillable pen device with Protaphane® Penfill® cartridges to reduce the need for education on two separate devices.

Clinicians must adhere to local policy regarding safe and accurate medication prescribing, dispensing and administration as well as independent second person checks where applicable. These checks should include (but are not limited to) carefully reading the medication label to verify the name, strength, form and route of administration against the medication order, rather than relying on packaging or label recognition.

Transition to alternative products

- Implement actions to prepare for and ensure the safe transition from Protaphane® InnoLet® device to reusable pen devices, in liaison with local clinicians.
- Orders for alternative products and refillable pen devices should be placed well in advance to ensure timely receipt and ongoing supply. There may be limits on the number of reusable devices that can be ordered at one time; consider the potential for increased demand to ensure adequate supply.
- Existing guidelines and protocols that include Protaphane® InnoLet® should be reviewed and updated with alternative insulin product(s).

Safe use of cartridges/reusable pens

- For insulin products not available in a disposable pen/device, use a cartridge loaded into a reusable pen device for subcutaneous administration.
- Where possible, insulin cartridges may be individually dispensed and loaded into an appropriate delivery device at the point of dispensing.
- When using an insulin cartridge in a reusable insulin pen, ensure:
 - 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 pen is primed by expelling 2 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.

- Novo Nordisk cartridges are only to be used with reusable NovoPen® devices. Instructions on the use of NovoPen® devices can be found on the company website. Examples include Novopen 4® and NovoPen® Echo. Other types of NovoPen® may also be available. Examples/ links to select resources:

- [Novopen 4® \(user guide\)](#)
- [NovoPen 4® \(video\)](#)
- [NovoPen Echo® \(user guide\)](#)
- [NovoPen Echo® \(video\)](#)

Staff/patient education

- Patients and caregivers should be provided with education on the appropriate insulin product, including instructions on the use of reusable pen devices.
- During the transition period, prescribers should consider the duration of treatment to determine whether the patient requires instructions for two different administration devices.
- The drug sponsor will provide support material to healthcare professionals to assist patients transitioning to alternative treatments closer to the discontinuation date of each product.

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Issue date

20/12/2024

Attachment 1: Insulin products to be discontinued and appropriate available alternatives*

Insulin type	Product(s) planned for discontinuation	Planned discontinuation date (Stock may be available after this date until supplies depleted)	Available alternative product(s)
Insulin aspart	Fiasp® FlexTouch® prefilled pen	1 March 2024	Fiasp® Penfill® cartridge
	Fiasp® vials	1 December 2024	
Insulin degludec + Insulin aspart 70/30	Ryzodeg® 70/30 FlexTouch® prefilled pen	1 February 2025	Ryzodeg® 70/30 Penfill® cartridge
Insulin isophane	Protaphane® InnoLet® prefilled pen	1 February 2025	Protaphane® vial Protaphane® Penfill® cartridge
	Protaphane® Penfill® cartridge	31 December 2026	Protaphane® vial
Insulin detemir	Levemir® Penfill® cartridge	31 December 2026	No like-for-like alternative available
	Levemir® FlexPen® prefilled pen		
Insulin neutral	Actrapid® Penfill® cartridge	31 December 2026	Humulin® R cartridge Actrapid® vial

* Note: Other long-acting insulins remain available and may be deemed appropriate on a case-by-case basis.