

Consensus advice for health services and clinicians following the discontinuation of Novo Nordisk’s InnoLet (Protaphane Insulin) Device: Immediate action required

On behalf of the Australasian Diabetes In Pregnancy Society (ADIPS), Australian Diabetes Educators Association (ADEA), Australian Diabetes Society (ADS), Diabetes Australia (DA), and Society of Obstetrics Medicine Australia and New Zealand (SOMANZ). We gratefully acknowledge contributions from the Royal Australian College of General Practitioners (RACGP) – Diabetes Specific Interests Group.

Background

Insulin isophane is an intermediate acting insulin with its effect starting at 60 minutes, a peak at 4-12 hours post injection and lasting up to 24 hours. In Australia, insulin isophane is currently available in vials, prefilled delivery devices and Penfill/pen cartridge formulations at 100 IU/mL marketed as Protaphane® (Novo Nordisk) and Humulin® NPH (Eli Lilly).

Novo Nordisk has recently announced a number of changes to its insulin portfolio internationally, that will impact availability of some products in Australia. This includes discontinuing the Protaphane prefilled InnoLet device from February 2025 and the Protaphane Penfill from December 2026 (please refer to the table below). Additional product discontinuations have also been announced and will be addressed in separate updates as required.

ACTIVE SUBSTANCE	BRAND NAME	PRESENTATIONS TO BE DISCONTINUED	ANTICIPATED END DATE OF PRODUCT AVAILABILITY	PRESENTATIONS REMAINING AVAILABLE
Isophane (NPH) insulin human	Protaphane	InnoLet (PBS listed)	February 2025	Penfill (until Dec 2026) and Vials (PBS listed)
Isophane (NPH) insulin human	Protaphane	Penfill (PBS listed)	December 2026	Vials (PBS listed)

Intent of this advice

This consensus advice has been developed to ensure that Australian clinicians who provide care for people living with diabetes are informed and prepared for the pending changes in product availability. Health services and clinicians should also keep up to date with advice from the [Therapeutic Goods Administration](#) and relevant local jurisdictional bodies. This advice does not constitute formal evidence-based clinical guidance, but rather consensus expert opinion regarding options in the context of changing product availability.

What does this mean?

After February 2025, people living with diabetes will no longer be able to access Protaphane InnoLet. To access insulin isophane, two options remain at present:

1. Protaphane® in a Penfill (cartridge) using a NovoPen4 reusable administration device
2. Humulin® NPH in a cartridge using a HumaPen reusable administration device

Otherwise, clinicians may consider prescribing alternative insulins. All patients prescribed insulin in Penfills/cartridges must be provided with a suitable insulin delivery device and appropriate education on how to safely use it.

Patient Groups Impacted

The main groups likely to be most impacted by the discontinuation of Protaphane InnoLet are:

- Women with gestational diabetes (GDM)
- People with steroid-induced hyperglycaemia
- Adult inpatients on enteral feeding
- Elderly or other people with impaired dexterity or vision

Recommendations

1. Prescribers should no longer initiate Protaphane InnoLet for new users
2. For patients currently prescribed Protaphane InnoLet, consider switching to either Protaphane Penfills (only available until December 2026) or Humulin NPH pen cartridges, or an alternative insulin, as soon as possible. People currently using Protaphane InnoLet for GDM or temporary steroid-induced hyperglycaemia may have sufficient supply to continue using Protaphane InnoLet. This should be assessed with each individual and a timely plan made to transition to an alternative insulin formulation if required.
3. It is recommended that you review your practice database as soon as possible to proactively identify any people utilising the Novo Nordisk InnoLet device and arrange a clinical review to support a switch to an alternative insulin as suggested below.
4. Consider the appropriateness of alternative insulins for your patient(s) (see table below). The Protaphane Penfill will be discontinued in December 2026. Humulin NPH pen cartridges are unlikely to match the increased demand should all insulin isophane users transfer to Humulin NPH. If clinical uncertainty about alternatives arises, seek specialist diabetes advice.
5. Ensure people have access to the correct reusable insulin pen for their prescribed insulin and are familiar with its use. If appropriate, provide the required education or refer to a credentialed diabetes educator for advice (refer to Further Resources below). For people with dexterity issues or poor vision, further education and assessment may be required. If necessary, a support person or family member may also need to be educated on using the insulin pen of choice.
6. Following any change in insulin regimen, advise regular home glucose monitoring and review patients promptly after any changes to ensure that they are using their new device appropriately and that their blood glucose is within their target range.

Scenario	Considerations for additional insulin options other than an alternative preparation of insulin isophane (e.g. Protaphane Penfill or Humulin NPH cartridge)
Gestational diabetes with fasting hyperglycaemia	<p>Optisulin (insulin glargine 100 IU/mL) is Pregnancy Category B3 but has been widely used in pregnancy. Availability of the Solostar prefilled, disposable pen device may have advantages in some contexts. The longer action time compared to insulin isophane must be considered.</p> <p>Given that Protaphane Penfills will be discontinued from December 2026, some services may choose to transition to Optisulin (insulin glargine 100 units/mL) sooner.</p> <p>For patients who also have post-prandial hyperglycaemia, mixed insulin products (e.g. Novomix30 or HumalogMix25) could be considered. Products containing insulin degludec (e.g. Ryzodeg 30/70) should be considered with caution due to potential risk of post-partum maternal hypoglycaemia.</p>
Steroid-induced hyperglycaemia	<p>For patients on dexamethasone or regular high dose hydrocortisone, Optisulin (insulin glargine 100 IU/mL) is appropriate.</p> <p>For patients on prednisolone and some women receiving betamethasone in pregnancy, insulin isophane is likely to remain a preferred option. Alternatives include mixed insulins with an intermediate acting component such as NovoMix30 or HumalogMix25. These can be prescribed with breakfast and, if needed, lunch for patients taking prednisolone in the morning.</p>
People with diabetes with limited dexterity or vision	None of the available insulin delivery devices is comparable to the InnoLet. Use of a prefilled disposable insulin pen may be simpler in this context. Additional supports may need to be advised.
Enteral feeding associated hyperglycaemia	The insulin regimen should be tailored to the feeding regimen. Insulin isophane is predominantly used in the context of continuous feeds for a limited period of the day (e.g. overnight feeds). Insulin isophane remains the preferred option. Other insulins may be more suitable for patients on bolus feeds or 24-hour continuous feeds.

Transitioning to a new insulin may affect a patient's blood glucose management. In circumstances where there is uncertainty in transitioning, clinicians are advised to seek advice from a specialist diabetes team or credentialed diabetes educator.

Accessing reusable insulin delivery devices

Please note: The insulin cartridges are brand specific and are not interchangeable with the other pen device. It is essential that people have the correct pen for the brand of insulin pen cartridges they obtain.

NovoPen® 4 will be available through Pharma Programs from 20th January 2025 for pharmacies to place orders. More than 96% of pharmacies across Australia are already enrolled in the program. Any healthcare professional can order directly from either Novo Nordisk Medical Information Team on aunrccc@novonordisk.com or 1800 668 626, or from their local Novo Nordisk Hospital Sales Representatives.

To order the HumaPen SAVVIO please email au_info@lilly.com or contact your local Eli Lilly Hospital Sales Representative.

Availability of insulin vials

Vial preparations for use with insulin syringes are available from both companies. However, most people have not had any experience with using insulin syringes and vials and would need specific instruction in their use. In addition, most people would be far better suited to using an insulin pen device, including if there are dexterity issues or impaired vision. Concerningly, it is likely that the requirement to use an insulin syringe and vial may reduce rates of insulin acceptance and thus substantially impede and delay optimisation of diabetes management.

Many hospitals have moved away from using insulin vials as a strategy to reduce insulin administration errors. Hospitals and health networks need to promptly review their formularies and guidance around insulin isophane delivery.

Further Resources

National Diabetes Services Scheme (NDSS) Gestational Diabetes and Me - <https://gdandme.ndss.com.au/>

Find-A-CDE – directory of CDEs in Australia: <https://www.adea.com.au/find-a-cde/>

Insulin Chat - free helpline for clinicians and patients, and staffed by Credentialed Diabetes Educators: <https://www.insulinchat.com.au/>

NSW Health safety notice on Discontinuation of multiple insulin products www.health.nsw.gov.au/sabs/Documents/2024-sn-035.pdf

Therapeutic Goods Administration About the discontinuation of the protaphane InnoLet insulin cartridges - <https://www.tga.gov.au/safety/shortages/information-about-major-medicine-shortages/about-discontinuation-protaphane-innolet-insulin-cartridges>

Therapeutic Goods Administration About the Serious Scarcity Substitution Instrument (SSSI) - www.legislation.gov.au/F2024L01648/asmade/text