



SAFETY NOTICE 023/25

Issue date:	23 September 2025		
Content reviewed by:	Medication Safety Expert Advisory Committee, Medication Shortage Assessment and Management team, endocrine and diabetes experts.		
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit		
KEY MESSAGE:	To inform NSW Health facilities of the discontinuation of multiple insulin products and associated safety considerations.		
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance		
REQUIRED ACTION:	 Distribute this Safety Notice to all relevant clinicians and clinical departments where insulin is held, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles. 		
	2. Undertake a local risk assessment and incorporate the below recommendations to manage the discontinuation of various insulin products.		
	3. Ensure a system is in place to document actions taken in response to this Safety Notice.		
	4. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims ⁺ .		
We recommend	Directors, Managers and Staff of:		
you also inform:	Endocrinology Departments		
	Diabetes/Endocrine Clinics		
	Pharmacy Services		
	Nursing/Midwifery		
	Medical Services		
	 Digital Health/Information and Communications Technology (ICT) 		
	Drug and Therapeutics Committees		
	All other relevant clinicians, departments and committees.		
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx		
	http://internal.health.nsw.gov.au/quality/sabs/index.html		
Review date:	February 2027		

Contact: Clinical Excellence Commission

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What is updated in the Safety Notice from SN:035/24?

This Safety Notice replaces SN:035/24 – Discontinuation of multiple insulin products, which has now been rescinded.

This Safety Notice has been expanded to provide clinicians with updated information on insulin products to be discontinued and advice for switching to alternative available products. Where possible, preference should be given to insulins available in disposable devices, due to the limited availability of reusable insulin pens and the need to conserve them for specific situations.

Situation

Multiple insulin products are being discontinued from the global market by Novo Nordisk. This discontinuation will affect the Australian 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, however consideration is to be given to individual patient factors and the availability of reusable pens where required.

Background

Insulin is a hormone produced by the pancreas and is responsible for the regulation of blood glucose levels. As a medication, insulin is used either to replace or supplement the body's own natural insulin. It is most commonly used in the treatment and management of diabetes, including type 1, type 2 and gestational diabetes. Various insulin products are available that differ in duration of onset and action, as well as presentation and method of administration.

Assessment

The TGA has released a <u>web statement</u> regarding the changes to the supply of multiple insulin products and the availability of alternatives. Refer to **Table 1** for a list of affected insulin products and available equivalent cartridge or vial alternatives.

Table 1: Affected insulin products and available equivalent cartridge or vial alternatives.

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Insulin product(s) to be discontinued	Planned discontinuation date*	Available equivalent alternative(s)	
Fiasp® (insulin aspart) FlexTouch® prefilled pen and vials	1 December 2024 (vials) 1 March 2025 (FlexTouch)	Fiasp (insulin aspart) Penfill® cartridge	
Ryzodeg® (Insulin degludec + insulin aspart 70/30) FlexTouch prefilled pen	1 February 2025	Ryzodeg® (Insulin degludec + insulin aspart 70/30) Penfill cartridge	
Actrapid® (insulin neutral) Penfill cartridge	31 December 2026	 Humulin® R (insulin neutral) cartridge Actrapid (insulin neutral) vial 	
Protaphane® (insulin isophane) InnoLet® prefilled pen and Penfill cartridge	1 February 2025 (Innolet) 31 December 2026 (Penfill)	Humulin NPH (insulin isophane) cartridgeProtaphane (insulin isophane) vial	
Levemir® (insulin detemir) FlexPen® prefilled pen and Penfill cartridge	31 December 2026	No like-for-like alternative available	

^{*}Note stock may be available after this date. Planned discontinuation dates are subject to change – refer to TGA web statement and drug sponsor for the most up to date information.

There is limited availability of reusable insulin pens due increased demand. Preference should be given to insulins available in disposable devices where appropriate.

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Recommendations

The recommendations below are intended for NSW Health facilities. They are to be considered and implemented in conjunction with the requirements of the NSW Health Policy Directive *Medication Handling* (PD2022_032), NSW Health Policy Directive *High-Risk Medicines Management* (PD2024_006) and the CEC High-Risk Medicines Standard: Insulin. Although these discontinuations may have a broader impact (for example, on primary or community settings), these recommendations may not be suitable for every setting.

Clinicians must adhere to local policy regarding safe and accurate medication administration, including the 5 Rights (right patient, right drug, right dose, right time, and right route) and 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. Refer to Sections 6.6 to 6.8 of NSW Health Policy Directive *Medication Handling* (PD2022_032) for more information.

Transition to alternative products

- Implement actions to prepare for and ensure the safe transition to the alternative insulin products and use of reusable pen devices where not previous used, in liaison with representatives from the local Endocrinology Service, Drug and Therapeutics Committee, Pharmacy and other relevant clinicians.
- Patients currently prescribed an insulin product due to be discontinued will need to be switched to an
 appropriate alternative insulin preparation under specialist advice. Preference should be given to
 switching to an alternative insulin that is available in a disposable device. Use of an insulin cartridge
 with a reusable pen should only be considered where no suitable disposable alternative is available,
 or where use of a disposable pen may not be appropriate. These include:
 - o Patients with significant insulin sensitivity requiring half-unit dosing, including children, adolescents, individuals with type 1 diabetes, or those with low BMI.
 - Patients with dexterity or visual impairment who may benefit from reusable pens with features such as larger dose displays and tactile feedback.
 - o Patients using multiple insulin types and/or complex regimens, where reusable pens offer features such as colour differentiation and dose memory to support safe administration.
 - o Individuals in remote communities, where reusable pens may help to reduce medical waste and simplify supply logistics by allowing multiple cartridges per device.
- Where possible patients can continue to use their own insulin cartridge with a reusable pen while in hospital (after ensuring the insulin is still within expiry), noting that once the cartridge is depleted, it will be replaced with a hospital-supplied cartridge. Ensure the patient's reusable pen is clearly labelled with their name.

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- The choice of an alternative insulin that is available in a disposable device will be dependent on individual patient factors and under specialist advice. See below examples of alternate insulin products (not a comprehensive list), noting they are not directly equivalent to the insulin types being discontinued:
 - Alternative rapid-acting insulins
 - NovoRapid® (insulin aspart) FlexPen®
 - Humalog® (insulin lispro) KwikPen®
 - Humalog® Mix25 (insulin lispro + insulin lispro protamine 25 units/mL) KwikPen®
 - Apidra® (insulin glulisine) SoloStar® pen
 - Alternative basal insulins
 - Optisulin® (insulin glargine) SoloStar® pen
 - For further guidance, refer to the <u>Consensus advice for health services and clinicians following the discontinuation of Novo Nordisk's InnoLet (Protaphane Insulin) Device:</u>
 Immediate action required.
- Orders for alternative insulin products and associated reusable pens should be placed early to ensure timely access for patients. Reusable pens can be ordered through local Novo Nordisk hospital representatives (for no cost at the time of publication) or by contacting Eli Lilly on 1800 454 559. For further information on the availability of reusable pens, please contact the drug sponsor(s).
- Pharmacy Departments, imprest rooms, after hour drug rooms, and automated dispensing cabinets (ADCs) should be reviewed and updated to include alternative product(s) and reusable pens and reflect appropriate stock counts.
- Clinical guidelines and protocols that include insulin should be reviewed and updated to reflect any changes associated with the use of the alternative insulin product(s).
- Governance committees should liaise with local electronic Medication Management (eMM)/ICT teams
 to update configurations (for example, order sentences and product catalogues) in the eMM system
 where required to reflect the change in product. Where eMM systems are in use, mechanisms should
 be built to prevent selection errors at the point of prescribing.

Safe use of cartridges/reusable pens

- All insulin for subcutaneous injection is to be administered via an insulin delivery device.
- 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 should be individually dispensed.
- Dispensing labels are to be affixed to the body of the insulin delivery device (not to the removable cap).
- Use a safety pen needle when administering insulin with a reusable pen to reduce risk of sharps injury. Refer to <u>CEC factsheet</u> Safe Administration of Medication Pen Devices – Information for Health Care Providers.

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- When using an insulin cartridge in a reusable insulin pen, ensure:
 - the insulin cartridge is loaded into the reusable pen in a way that the medicine name is clearly visible through the 'window' of the delivery device
 - the insulin cartridge is loaded and properly 'engaged' within the insulin pen by priming appropriately. If the cartridge is dispensed by Pharmacy, it is recommended that the 'engagement' of the cartridge occurs at the point of dispensing
 - o 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
 - the insulin cartridge is checked before each administration (without removing it from the reusable pen), to confirm the correct insulin is selected and it is within the expiry date. Refer to the <u>CEC High-Risk Medicines Standard: Insulin</u> for requirements regarding the labelling of insulin products, including patient details and expiry date.
- Novo Nordisk and Eli Lilly (Humulin R and Humulin NPH) cartridges are only to be used with the NovoPen® and HumaPen® reusable pens respectively. For instructions on the use of reusable pens, refer to:
 - o NovoPen® 4
 - o NovoPen® 6
 - NovoPen Echo®
 - HumaPen SAVVIO®

Note: other types of NovoPen and HumaPen may be available.

The expiry date of reusable pens should be checked before use. If using the patient's own device, ensure to ask when they first started using it. NovoPen® devices have a lifespan of 4 to 5 years, while HumaPen SAVVIO pens should not be used for more than 6 years after first use or beyond the expiration date on the carton.

Staff/patient education

- 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.
- Patients and caregivers should be provided with appropriate education on the alternative insulin product, including information and instructions on the use of reusable pen devices. This information should be clearly documented during transitions of care (for example, on discharge).

Further information

- Diabetes Australia Diabetes quick guides: Insulin
- National Diabetes Services Scheme Factsheet: Insulin