NSW Health

Discontinuation of multiple insulin products

SAFETY NOTICE 035/24

Issue date:	16 December 2024
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:	1. 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+. 5. Confirm receipt and distribution of this Safety Notice within **72 hours** to: CEC-MedicationSafety@health.nsw.gov.au.
DEADLINE:	19 December 2024
We recommend you also inform:	Directors, Managers and Staff of: • Endocrinology Departments • Diabetes/Endocrine Clinics • Pharmacy Services • Nursing/Midwifery • Medical Services • Digital Health/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:	December 2025

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au

Discontinuation of multiple insulin products

N SN:035/24

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.

Background

Insulin is a hormone produced by the pancreas and is responsible for the regulation of blood glucose levels.

Insulin, as a medication, 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 web statement regarding the upcoming changes to the supply of multiple insulin products and the availability of alternatives. The TGA will continue to inform patients and health care professionals about any changes to this situation through alerts and updates on their website. Refer to **Table 1** for a list of the insulin products being discontinued and available alternatives.

Table 1: Insulin products to be discontinued, and appropriate available alternatives.

Insulin product(s) to be discontinued	Planned discontinuation date (stock may be available after this date, until depleted)#	Available 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) **cartridge** • Protaphane (insulin isophane) **vial**
Levemir® (insulin detemir) FlexPen® prefilled pen and Penfill cartridge	31 December 2026	**No like-for-like alternative available***

#Note planned discontinuation dates are subject to change – refer to TGA web statement and drug sponsor.
*Other long-acting insulins remain available and may be deemed appropriate on a case-by-case basis.

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Patients currently prescribed an insulin product due to be discontinued will need to be switched to an appropriate alternative insulin preparation. This may include switching patients to a different insulin type which continues to be available in a disposable prefilled device, or use of the same insulin administered via a cartridge loaded in a reusable pen (if available). Insulin vials must only be used in certain circumstances, as outlined in the CEC High-Risk Medicines Standard: Insulin.

The choice of alternative will be dependent on individual patient factors, and where necessary advice should be sought from the diabetes management team.

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 6 Rights (right patient, right drug, right dose, right time, right route and right documentation) 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 Pharmacy and Endocrinology Departments, Drug and Therapeutics Committee, and relevant clinicians.
- Orders for alternative products and reusable pens should be placed well in advance to ensure timely receipt and ongoing supply. 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.

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- 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 CEC factsheet Safe Administration of Medication Pen Devices – Information for Health Care Providers.
- 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
    - 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 CEC High-Risk Medicines Standard: Insulin 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:
    - NovoPen® 4
    - NovoPen Echo®
    - HumaPen SAVVIO®

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

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

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