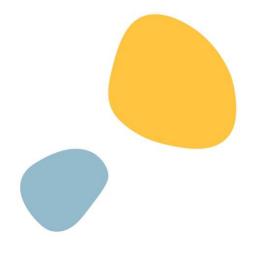
Medication Safety Notification

4 February 2025

Discontinuation of multiple insulin products

Classification: Official





Medication Safety Notification

4 February 2025

Discontinuation of multiple insulin products

This information has been distributed to provide advice to WA health professionals of potential safety issues. A risk assessment is required at a local level to determine the impact and relevance of this information and the response required.

Issue:

- 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:

- The Therapeutics Goods Administration (TGA) has released a <u>web statement</u> 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 **Attachment 1** for a list of the insulin products being discontinued and available alternatives.
- 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).
- The choice of alternative will be dependent on individual patient factors, and where necessary advice should be sought from the diabetes management team.
- The Australian Commission on Safety and Quality in Health Care have developed clinician and consumer fact sheets to support health professionals with the transition requirements.

Fact Sheet for clinicians: Discontinuation of insulin products – strategies and safety considerations.

<u>Discontinuation of Protaphane Innolet®- strategies and safety considerations</u>

Fact Sheet for consumers: Important changes for people who use insulin

Consensus advice has been prepared 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) for health
services and clinicians following the discontinuation of Novo Nordisk's Innolet (Protaphane insulin) Device.

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.
- 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 insulin cartridge is checked before each administration (without removing it from the reusable pen), to confirm it contains the correct insulin and it is within the expiry date.
 - 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.

Actions:

- Disseminate this notification to relevant clinicians and clinical departments where insulin is held, prescribed and administered.
- Table this notification at your local Medicine and Therapeutics Committee or equivalent.

The information in this alert is provided in good faith for the purpose of identifying possible safety issues and risks to facilitate improvements in safety and quality of health care. While every reasonable effort has been made to ensure the accuracy of the alert, no guarantee can be given that its contents are (1) free from error or omissions, or (2) current at the time you access it.

The State of Western Australia, the Minister for Health and the Department of Health and their officers, employees and agents expressly disclaim liability for any act of omission occurring in reliance on the information in the notification and for any consequences of such act or omission.

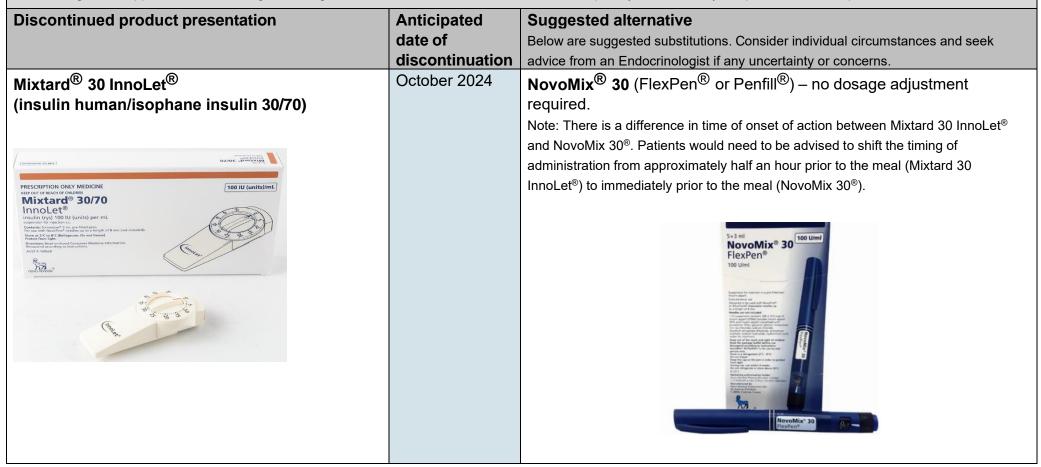
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Clinical Excellence Division
Department of Health, Western Australia

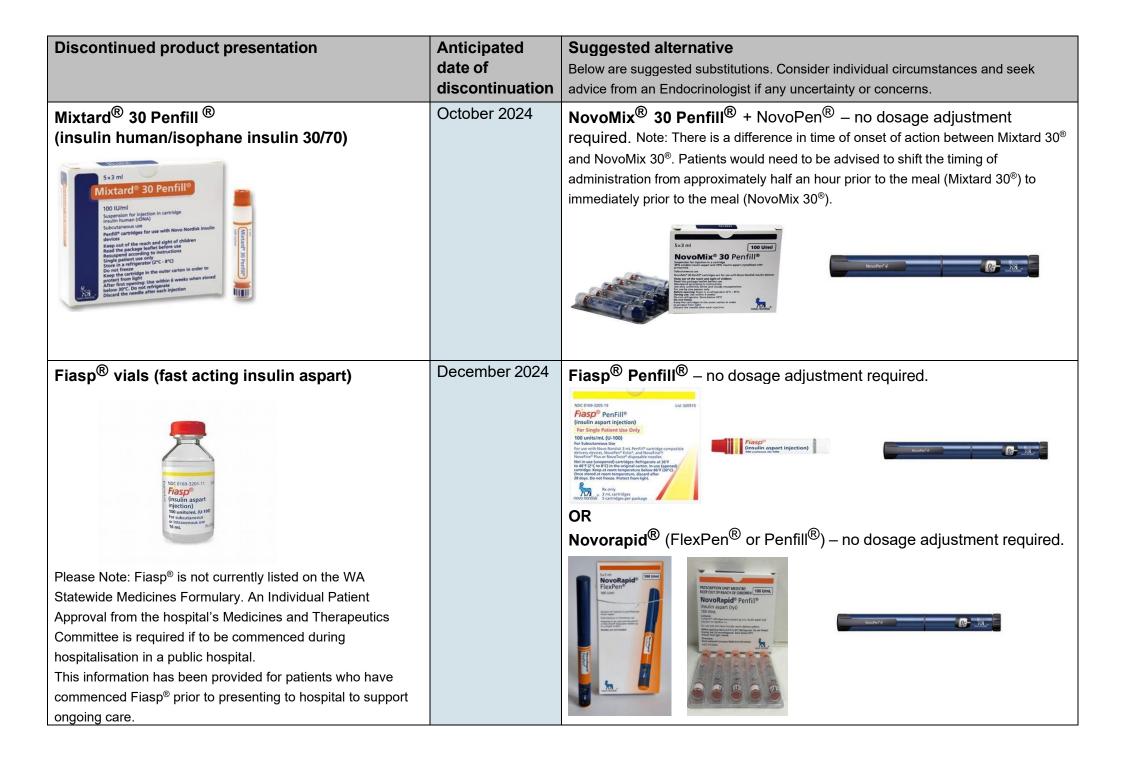
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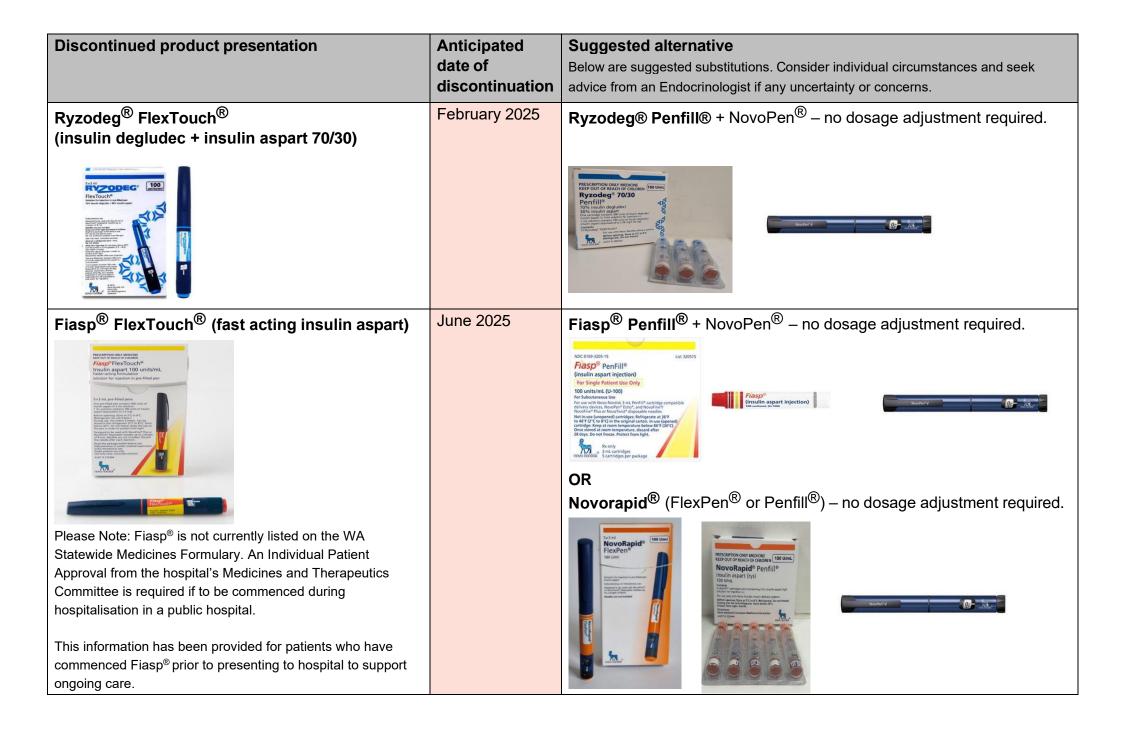
Attachment 1: Discontinuation notice of Novo Nordisk insulin product presentations.

Information in this attachment is correct as of 4 February 2025. Please also refer to the <u>Therapeutic Goods Administration (TGA) website</u> for further information. WA Health acknowledges and appreciates the sharing of the original content for this document that was developed by Fiona Stanley Hospital that was adapted for this table.





Discontinued product presentation	Anticipated date of discontinuation	Suggested alternative Below are suggested substitutions. Consider individual circumstances and seek advice from an Endocrinologist if any uncertainty or concerns.
Protaphane® InnoLet® (isophane insulin human) (InnoLet® Of the total of columns Protaphane® InnoLet® Of the total of the	February 2025	1. Protaphane® Penfill® + NovoPen® – no dosage adjustment required. Pescription only Medicine Too Blank Protaphane® Penfill® 3 mL Israiling 70 to 10 undrag beautiful as a cartridge using a HumaPen reusable administration device. Prospective and the state of the



NovoNordisk has also indicated that the following insulins will be discontinued as of December 2026

Protaphane Penfill (isophane (NPH) insulin human)



Levemir® Penfill® cartridge (Insulin determir) Levemir® FlexPen® prefilled pen



Actrapid® Penfill® cartridge (Insulin neutral)



Medicines and Technology Unit Patient Safety and Clinical Quality Directorate Clinical Excellence Division Department of Health, Western Australia

E: DoH.MedicinesandTechnology@health.wa.gov.au

This document can be made available in alternative formats on request for a person with disability.

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