

MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

UPDATED Insulin degludec 70% with insulin aspart 30 % (Ryzodeg® 70/30 FlexTouch®) pre-filled pens – 2 August 2023	
Details of affected product(s)	Insulin degludec 70% with insulin aspart 30% (Ryzodeg 70/30) FlexTouch preloaded injector – ARTG 280432
Reason for communication	Disruption to supply
Date issue made apparent	June 2023
Estimated resolution date	June 2024
What has been updated?	Additional advice surrounding individual dispensing and loading of cartridges into an appropriate delivery device at the point of dispensing.

Main indications and use

Insulin degludec 70% with insulin aspart 30% (Ryzodeg 70/30) is a co-formulated insulin used in the treatment of type 1 and type 2 diabetes mellitus in patients aged 6 years and older. Ryzodeg 70/30 is a soluble, biphasic insulin consisting of the ultra-long-acting basal insulin degludec and the rapid-acting prandial insulin aspart in a ratio of 70:30.

Situation

There is a long-term disruption to the supply of Ryzodeg 70/30 FlexTouch pre-filled pens until June 2024 due to unprecedented global demand. The drug sponsor (Novo Nordisk) has confirmed supply of Ryzodeg 70/30 Penfills (cartridge) are **not** affected. The Therapeutic Goods Administration has made a Serious Scarcity Substitution Instrument (SSSI) which allows community pharmacists to dispense Ryzodeg 70/30 Penfills (cartridge) where Ryzodeg 70/30 FlexTouch has been prescribed, without the need for prior approval to substitute from the prescriber. The SSSI will be in place until 5 June 2024 (unless revoked earlier). Further information about the substitution and the conditions required can be found [here](#).

Alternative agents

- Alternate pen delivery devices for example, NovoPen® delivery devices are available for the administration of Ryzodeg 70/30 Penfills (cartridge). The reusable NovoPen delivery devices can be ordered through local Novo Nordisk hospital representatives at no cost.
- Alternative products containing insulin degludec 70% with insulin aspart 30% registered internationally are available under the Special Access Scheme (SAS) of the Therapeutic Goods Act from Orspec and Link. Other suppliers may have SAS alternatives in future.
- Alternative co-formulated insulin, for example NovoMix® 30, can also be considered as an alternative in consultation with the patient's Endocrinologist.

Precautions, safety issues and other considerations associated with alternatives

Administration of Ryzodeg 70/30 Penfills via NovoPen delivery devices

NovoPen delivery devices can be used in conjunction with Ryzodeg 70/30 Penfills (cartridge). While the active ingredient remains the same, insulin is a high-risk medicine and the change in administration device has potential safety implications.

Where possible, Ryzodeg 70/30 Penfills should be **individually dispensed** and loaded into an appropriate delivery device at the point of dispensing. Care should be taken to ensure the cartridge is loaded in a way that the medicine name is clearly visible through the 'window' on the delivery device, and that the plunger in the device is 'engaged' by priming appropriately.

Clinicians should be advised:



- The practice of drawing up insulin with a syringe is strongly discouraged due to an increased risk of needle-stick injuries, and potential for contamination of the cartridge and inaccurate dosing.
- Safety pen needles are to be used by administering clinicians with the NovoPen delivery device. Further information on the safe administration of medication pen devices can be found [here](#).

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- The delivery device is to be primed, by expelling 2 units of insulin prior to dialling up the required dose, to ensure an accurate dose is delivered.
- An independent second check is to be employed when administering insulin in accordance with the NSW Health Policy Directive *Medication Handling* (PD2022_032).
- There are slight differences between administration techniques between the FlexTouch pen and NovoPen delivery devices. Clinicians should be educated on how to use the NovoPen delivery devices including the need to extend (pull out) the dose button before dialling up the dose. Further information on how to use the NovoPen delivery devices can be found on this [page](#).
- Patients who require supply of Ryzodeg 70/30 via a NovoPen delivery device on discharge should be:
 - educated (preferably by a Diabetes Educator) on how to use the device, using the [Teach Back](#) or similar method
 - provided with initial supply of a NovoPen delivery device, pen needles and Ryzodeg 70/30 Penfill (cartridge)
 - be advised for ongoing supply they will need to obtain a prescription from their General Practitioner if they don't already have one.
- See **Table 1** below for a comparison of the FlexTouch pen and NovoPen delivery devices.

Table 1. Comparison of FlexTouch pen and NovoPen delivery devices

	FlexTouch pen	NovoPen delivery devices
Pen device	Pre-filled syringe for single patient use (not reusable).	Pen injector to be loaded with Penfill® cartridges for single-patient use (reusable for the same patient).
Prime device before use	Yes	Yes
Dial	Non-extending dose button	Pull out (extend) dose button before dialling up dose
Increment dosing	1 unit increments	1 unit increments or 0.5 unit increments with NovoPen® Echo
Memory function	No	Yes – NovoPen® 6 and NovoPen® Echo
Compatible needles	For example, NovoFine® and NovoTwist® needles (other needles may be compatible)	
Max single-dialled dose	80 units	60 units (except 30 units with NovoPen® Echo)
Storage	Before use – 2 – 8°C. After opening – below 30°C for up to 28 days.	Without Penfill cartridge – store at room temperature. With Penfill cartridge – store as per Penfill cartridge storage instructions.
Image		Example: NovoPen® 4 

Insulin degludec 70% with insulin aspart 30% via Special Access Scheme (SAS)

- The SAS products are identical in the active ingredient, device, strength, method of administration, excipients, storage, and shelf-life to the Australian registered product.
- The cost of this alternative may be prohibitive for some facilities, and consideration should be given to continuity of supply in the community setting as it is not listed on the Pharmaceutical Benefits Scheme.

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Other considerations

Clinicians obtaining a medication history from patients on Ryzodeg 70/30 prior to admission should document the name of the delivery device used and remaining supply available at home. Care is to be taken to prevent confusion which switching between delivery devices.

Impacts of this communication on clinical practice

Actions to address the disruption to the supply of Ryzodeg 70/30 FlexTouch pens should be planned and implemented at a local level by the Drug and Therapeutics Committee in consultation with the relevant clinicians. Alternatives are available and can be utilised by facilities after consideration of the above precautions and safety issues in addition to individual patient needs.

Associated regulatory or policy issues

[PD2022_032 Medication Handling](#)

[PD2019_019 Coordination of responses to urgent system-level medicine or medical device issues](#)

Key contacts

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