

backgrounder

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About Ryzodeg® (insulin degludec / insulin aspart)

What is Ryzodeg®?

- Discovered and developed by Novo Nordisk, Ryzodeg® is the first combination of two distinct insulin analogues, Tresiba® (insulin degludec), the once-daily basal insulin with an ultra-long duration of action, and the well-established mealtime insulin NovoRapid® (insulin aspart) in the ratio of 70% and 30%¹.
- The basal component, Tresiba®, is the first basal insulin analogue that can be combined in a soluble solution with a mealtime insulin (NovoRapid®)^{2,3}.
- No re-suspension of Ryzodeg® is required and the formulation in the pen is ready to inject. The formulation does not precipitate and is visibly clear.
- Ryzodeg® provides flat and stable basal coverage with mealtime control in one pen¹.
- Ryzodeg® delivered twice-daily at main meals offers successful reductions in HbA_{1c}¹ with lower rates of hypoglycaemia versus biphasic insulin aspart 30 in people with type 2 diabetes, showing⁴:
 - 32% lower rate of confirmed overall hypoglycaemia
 - 73% lower rate of confirmed night-time hypoglycaemia
 - 89% lower rate of severe hypoglycaemia in the maintenance period*

Who is Ryzodeg® for?

- Ryzodeg® is licensed for use by people with type 1 and 2 diabetes¹ and is an alternative to separate basal and bolus injections and premix insulin.

How is Ryzodeg® administered?

- In the EU, Ryzodeg® can be administered once- or twice-daily with the main meal(s)¹.
- In Japan, Ryzodeg® can be administered twice-daily just before breakfast and dinner or once-daily, just before the large meal, the same meal every day⁵.
- Ryzodeg® is delivered in FlexTouch®, the only prefilled pen with an easy touch button⁶ and in Penfill®, which are insulin cartridges that are designed to be used with Novo Nordisk insulin delivery systems¹.

Regulatory status

- To date, Ryzodeg® has received regulatory approval in Japan, Mexico, EU, Norway, Iceland, Switzerland, El Salvador and Chile.

Clinical development programme

- The clinical trial programmes for Tresiba® (BEGIN™) and Ryzodeg® (BOOST™) comprise the largest in the field of insulin therapy, with more than 11,000 people included. They consisted of 17 randomised, controlled, treat-to-target trials in more than 40 countries and 1,000 clinical sites.
- The BOOST™ clinical trial programme specifically consisted of six randomised, controlled, treat-to-target trials in which 2,413 people were included.

* The maintenance period is defined as 16 weeks and beyond.

References

1. Ryzodeg® Summary of Product Characteristics 2013.
2. Jonassen I, *et al.* Ultra-long acting insulin degludec can be combined with rapid-acting insulin aspart in a soluble co-formulation. *J Peptide Sci* 2010;16(Suppl.1):32.
3. De Rycke A, *et al.* Degludec – first of a new generation of insulins. *Eur Endocrinol* 2011;7:84-7.
4. Fulcher G, *et al.* Superior FPG control and reduced hypoglycaemia with IDegAsp vs BIAsp 30 in adults with type 2 diabetes mellitus inadequately controlled on pre/self-mixed insulin: a randomised phase 3 trial. *Diabetologia* 2013;56(Suppl.1):S419-20 (abstract 1044).
5. Ryzodeg Japan Label 2012.
6. Hemmingsen H, *et al.* A prefilled insulin pen with a novel injection mechanism and a lower injection force than other prefilled insulin pens. *Diabetes Technol Ther* 2011;13:1207-11.