

# Experience the freedom\*

Up to now, Ryzodeg® is the first and only 2-in-1 insulin co-formulation providing basal and mealtime glycaemic control<sup>1-5</sup>



Once or twice daily dosing with main meals<sup>1</sup>



Targets both FPG and PPG for glycaemic control<sup>1</sup>



A flexible dosing regimen that can give patients the confidence to manage their treatment<sup>1,6-9</sup>



\*with flexibility in dose timing when dosed with main meal(s)

This image is a model and not a real patient.

Are you ready to discover how much you and your patients can achieve with Ryzodeg®?



#### Abbreviated prescribing information.

**Ryzodeg® (insulin degludec/insulin aspart) 100 units/mL insulin solution for injection in a pre-filled pen (FlexTouch®).** Consult Summary of Product Characteristics before prescribing. **Presentations:** Ryzodeg® FlexTouch®, The presentation contains insulin degludec/insulin aspart, Ryzodeg® - 1 mL solution contains 100 units insulin degludec/insulin aspart in the ratio 70/30 (equivalent to 2.56 mg insulin degludec and 1.05 mg insulin aspart). One pre-filled device contains 300 units of Ryzodeg® in 3 mL solution. **Indications:** Treatment of diabetes mellitus in adults, adolescents and children from the age of 2 years. **Posology and administration:** Ryzodeg® can be administered once- or twice-daily with the main meal(s). In patients with type 2 diabetes mellitus, Ryzodeg® can be administered alone, in combination with oral anti-diabetic medicinal products, and in combination with bolus insulin. In type 1 diabetes mellitus, Ryzodeg® is combined with short-/rapid-acting insulin at the remaining meals. Administration by subcutaneous injection only. Ryzodeg® should be dosed in accordance with individual patient needs. Dose adjustments are recommended to be primarily based on FPG measurements. Ryzodeg® allows for flexibility in the timing of insulin administration as long as it is dosed with the main meal(s). If a dose of Ryzodeg® is missed, the patient can take the missed dose with the next main meal of that day and thereafter resume the usual dosing schedule. Patients should not take an extra dose to make up for a missed dose. In older patients and patients with renal and/or hepatic impairment, glucose-monitoring should be intensified and the insulin dose adjusted on an individual basis. In paediatric population, when changing from another insulin regimen to Ryzodeg®, dose reduction of total insulin needs to be considered on an individual basis, in order to minimise the risk of hypoglycaemia. Ryzodeg® should be used with special caution in children 2 to 5 years old because data from the clinical trial indicate that there may be a higher risk for severe hypoglycaemia in children in this age group. Ryzodeg® comes in a pre-filled pen (FlexTouch®) designed to be used with NovoFine® or NovoTwist® injection needles. The pre-filled pen delivers 1-80 units in steps of 1 unit. The dose counter shows the number of units dialled. **Initiation:** For patients with type 2 diabetes mellitus, the recommended daily starting dose of Ryzodeg® is 10 units with meal(s) followed by individual dosage adjustments. For patients with type 1 diabetes mellitus, the recommended daily starting dose of Ryzodeg® is 60-70% of the total daily insulin requirement, to be used once-daily at meal time, in combination with short-/rapid-acting insulin at the remaining meals, followed by individual dosage adjustments. **Transfer:** Close glucose monitoring is recommended during transfer and in the following weeks. Doses and timing of concurrent rapid-acting or short-acting insulin products or other concomitant antidiabetic treatment may need to be adjusted. For patients with type 2 diabetes mellitus: those switching from once-daily basal or premix insulin can be converted unit-to-unit to once-daily Ryzodeg® at the same total daily insulin dose; those switching from more than once-daily basal or premix insulin can be converted unit-to-unit to twice-daily Ryzodeg® at the same total daily insulin dose; those switching from basal/bolus insulin to Ryzodeg® should convert their dose based on individual needs, in general with the same number of basal units. For patients with type 1 diabetes mellitus, the recommended starting dose of Ryzodeg® is 60-70% of the total daily insulin requirements in combination with short-/rapid-acting insulin at the remaining meals, followed by individual dosage adjustments. **Contraindications:** Hypersensitivity to the active substances or any of the excipients. **Special warnings and precautions:** Too high insulin dose, omission of a meal or unplanned strenuous physical exercise may lead to hypoglycaemia. In children, extra care should be taken to match insulin doses with food intake and physical activities in order to minimise the risk of hypoglycaemia. Ryzodeg® may be associated with higher occurrence of severe hypoglycaemia compared to a basal-bolus regimen in paediatric population, particularly in children 2 to 5 years old. For this age group, Ryzodeg® should be considered on an individual basis. Patients whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycaemia and must be advised accordingly. Usual warning symptoms may disappear in patients with long-standing diabetes. Inadequate dosing and/or discontinuation of treatment in patients requiring insulin may lead to hyperglycaemia and potentially to diabetic ketoacidosis. Concomitant illness, especially infections, may lead to hyperglycaemia and thereby cause an increased insulin requirement. Transferring to a new type, brand, or manufacturer of insulin must be done under strict medical supervision. When using insulin in combination with pioglitazone, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Hypoglycaemia may constitute a risk when driving or operating machinery. **Pregnancy and lactation:** There is no clinical experience with use of Ryzodeg® in pregnant women or in those who are breastfeeding. **Undesirable effects:** Refer to SmPC for complete information on side effects. Very common (>1/10); common (>1/100 to <1/10); uncommon (>1/1,000 to <1/100); rare (>1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data). Very common: Hypoglycaemia. Common: Injection site reactions. Not known: Lipodystrophy. Uncommon: Peripheral oedema and rare: Hypersensitivity and urticaria. With insulin preparations, allergic reactions may occur; intermediate-type allergic reactions may potentially be life threatening. Injection site reactions are usually mild, transitory and normally disappear during continued treatment. **Pharmacotherapeutic group:** Drugs used in diabetes. Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting.

**References:** 1. Ryzodeg® Summary of product insert. 2. Vijan S, et al. J gen Intern Med. 2005;20(5):479-482. 3. Fulcher G, et al. Diabetes Care. 2014;37(8):2084-2090. 4. Haahr H, et al. Clin Pharmacokinet. 2017;56(4):339-354. 5. Local IQVIA data. Q1 2020. 6. Kumar A, et al. Int J Clin Pract. 2016;70(8):657-667. 7. Peyrot M, et al. Diabetes Care. 2010;33(2): 240-245. 8. Fujimoto K, et al. Diabetol Metab Syndr. 2018;10:64. 9. Kaneko S, et al. Diabetes Res Clin Pract. 2015;107(1):139-147.



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**RYZODEG®**

70% insulin degludec and 30% insulin aspart  
[rDNA origin] injection

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