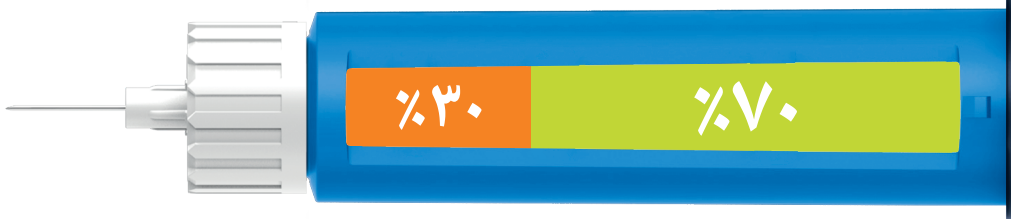


# رایزودگ®

اولین و تنها انسولین کو-فرمولاسیون به شکل یک محلول شفاف است، که ترکیبی از انسولین بیزال بسیار طولانی اثر دگلودک (Insulin Degludec) و انسولین بولس سریع الاثر آسپارت (Insulin Aspart) می باشد.<sup>۱،۲</sup>



رایزودگ® شامل:

یک انسولین بیزال با اثر بسیار طولانی  
و یک انسولین بولس سریع الاثر<sup>۲</sup>

۳۰%

انسولین آسپارت

انسولین آنالوگ بولس سریع الاثر  
با سال ها تجربه موفق بالینی  
می باشد.<sup>۱</sup>

۷۰%

انسولین دگلودک

انسولین آنالوگ بسیار طولانی  
اثر که در ترکیب با انسولین  
بولس سریع الاثر آسپارت  
بصورت محلول شفاف است.<sup>۲</sup>

# Once Daily RYZODEG®

## REFERENCES

1. Havelund et al. Pharm Res. 2015;32:2250-8. 2. Haahr H, et al. Clin Pharmacokinet. 2017;56(4):339-354.

**Abbreviated prescribing information: Ryzodeg®**, Insulin degludec/insulin aspart  
**Consult Summary of Product Characteristics before prescribing.**

**Presentations:** Ryzodeg® FlexPen® All presentations contain 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® is to be dosed in accordance with the individual patient's needs. Dose-adjustments are recommended to be based on fasting plasma glucose measurements. Adjustment of dose may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness. In patients with type 2 diabetes mellitus, Ryzodeg® can be administered once or twice daily with the main meal(s) alone, in combination with oral antidiabetic medicinal products, and in combination with bolus insulin. When using Ryzodeg® once daily, changing to twice daily should be considered when higher doses are needed, e.g. to avoid hypoglycemia. Split the dose based on individual patient's needs and administer with main meals. In patients with type 1 diabetes mellitus, Ryzodeg® can be administered once daily at mealtime in combination with short-/rapid-acting insulin at the remaining meals. Administration by subcutaneous injection only in the abdominal wall, the upper arm or the thigh. 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 pediatric 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 minimize the risk of hypoglycemia. 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 hypoglycemia in children in this age group. Ryzodeg® comes in a pre-filled pen (FlexPen®) designed to be used with NovoFine® injection needles. The pre-filled pen delivers 1-60 units in steps of 1 unit. The dose counter shows the number of units dialed. **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 mealtime, 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 anti diabetic treatment may need to be adjusted. For patients with type 2 diabetes mellitus: those switching from once daily basal or pre-mix insulin can be converted unit-to-unit to once or twice daily Ryzodeg® at the same total daily insulin dose; those switching from more than once-daily basal or pre-mix insulin can be converted unit-to-unit to once or 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. 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Patients whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycemia 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 hyperglycemia and potentially to diabetic ketoacidosis. Concomitant illness, especially infections, may lead to hyperglycemia and thereby cause an increased insulin requirement. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. 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 edema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Hypoglycemia 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 the SmPC for complete information on side effects. Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ), not known (cannot be estimated from the available data). Very common: Hypoglycemia. Common: Injection site reactions. Uncommon: Peripheral edema. Rare: Hypersensitivity and Urticaria. Not known: Lipodystrophy and Cutaneous amyloidosis. With insulin preparations, allergic reactions may occur; immediate-type allergic reactions may potentially be life threatening. Injection site reactions are usually mild, transitory and normally disappear during continued treatment. **Pharmaco-therapeutic group:** Drugs used in diabetes. Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting, ATC code: A10AD06. **Marketing authorization holder:** Novo Nordisk Pars, 14th Floor, Kian Tower, No.2551, Upper Shahid Dastgerdi, Vali-e-Asr Ave., Tehran, Iran. **Manufactured by:** Novo Nordisk Pars, Kordan, 10th Km Qazvin-Karaj Highway, Alborz Province, Iran. **IRC:** 2757573735625104. **Date of Review of Prescribing Information:** Locally Patient-Friendly label in Iran version Dec-2020, Eu-SmPC Sep-2021.

Ryzodeg®, FlexPen® and NovoFine® are trademarks owned by Novo Nordisk A/S, Denmark.

کدستی: ۱۹۶۸۴۳۱۹۵ تلفن: ۸۸۴۵۲۲۱ فکس: ۸۸۴۵۲۲۰

شرکت نوو نورددیسک پارس: تهران، خیابان ولیعصر، خیابان ناصری، ساختمان کیان، شماره ۲۵۵۱، طبقه ۱۴



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

# Introducing the New Generation Insulin

First and only innovative 2 in 1 **insulin Co-formulation** in the world<sup>1,3</sup>

## Co-formulation

Refers to the process of combining two or more active ingredients or components into a single product or formulation<sup>2</sup>

**30%**

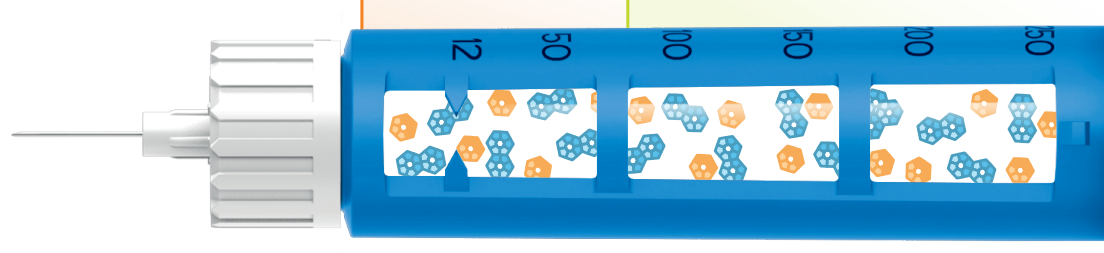
### INSULIN ASPART

Mealtime insulin analogue with over two decades of clinical experience<sup>1,3</sup>

**70%**

### INSULIN DEGLUDEC

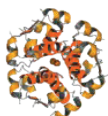
First **ultra long acting basal** insulin analogue that can be combined in a soluble solution with a mealtime insulin<sup>1</sup>



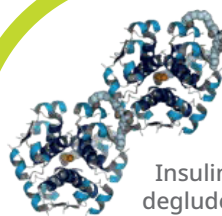
IAsp hexamers



IAsp  
hexamer  
(30%)



Insulin degludec  
dihexamers



Insulin  
degludec  
dihexamer  
(70%)

**IDegAsp**  
Insulin degludec (70%) +  
IAsp (30%) existing separately  
in one formulation<sup>1</sup>

IAsp, insulin aspart; IDegAsp, insulin degludec/insulin aspart



**RYZODEG**<sup>®</sup>

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

# A new treatment Simplify complex insulin regimens with the innovation of Co-formulation<sup>3</sup>



## 2-in-1 Co-formulation



Basal



Basal-bolus



Premix

**References:** 1. Havelund et al. Pharm Res. 2015;32:2250-8. 2. Chauhan VM, Zhang H, Dalby PA, Aylott JW. J Control Release. 2020;327:397-405. 3. Haahr H, et al. Clin Pharmacokinet. 2017;56(4):339-354.

**Abbreviated prescribing information: Ryzodeg<sup>®</sup>, Insulin degludec/insulin aspart**  
**Consult Summary of Product Characteristics before prescribing.**

**Presentations:** Ryzodeg<sup>®</sup> FlexPen<sup>®</sup> All presentations contain insulin degludec/insulin aspart. Ryzodeg<sup>®</sup> - 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<sup>®</sup> in 3 mL solution. **Indications:** Treatment of diabetes mellitus in adults, adolescents and children from the age of 2 years. **Posology and administration:** Ryzodeg<sup>®</sup> is to be dosed in accordance with the individual patient's needs. Dose-adjustments are recommended to be based on fasting plasma glucose measurements. Adjustment of dose may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness. In patients with type 2 diabetes mellitus, Ryzodeg<sup>®</sup> can be administered once or twice daily with the main meal(s) alone, in combination with oral antidiabetic medicinal products, and in combination with bolus insulin. When using Ryzodeg<sup>®</sup> once daily, changing to twice daily should be considered when higher doses are needed, e.g. to avoid hypoglycemia. Split the dose based on individual patient's needs and administer with main meals. In patients with type 1 diabetes mellitus, Ryzodeg<sup>®</sup> can be administered once daily at mealtime in combination with short-rapid-acting insulin at the remaining meals. Administration by subcutaneous injection only in the abdominal wall, the upper arm or the thigh. Ryzodeg<sup>®</sup> allows for flexibility in the timing of insulin administration as long as it is dosed with the main meal(s). 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The pre-filled pen delivers 1-60 units in steps of 1 unit. The dose counter shows the number of units dialed. **Initiation:** For patients with type 2 diabetes mellitus, the recommended daily starting dose of Ryzodeg<sup>®</sup> 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<sup>®</sup> is 60-70% of the total daily insulin requirement, to be used once daily at mealtime, 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 anti diabetic treatment may need to be adjusted. 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شركت نوو نورديسك پارس: تهران، خيابان وليعصر، خيابان ناصري، ساختمان كيان، شماره 2551، طبقه 14 كودپستی: ۱۹۶۸۴۳۱۹۵ تلفن: ۸۸۴۴۵۲۱۱ فکس: ۸۸۴۵۲۲۰



# RYZODEG<sup>®</sup>

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

# انسولین رایزودگ® هم اکنون در سراسر داروخانه‌های کشور موجود می‌باشد.

قلم بدون درپوش



قلم با درپوش



رایزودگ® اولین و تنها انسولین کو-فرمولاسیون به شکل یک محلول شفاف است، که ترکیبی از انسولین بیزال بسیار طولانی اثر دگلودک (Insulin Degludec) و انسولین بولس سریع الاثر آسپارت (Insulin Aspart) می‌باشد.<sup>۱،۲</sup>

**REFERENCES:** 1. Havelund et al. Pharm Res. 2015;32:2250–8. 2. Haahr H, et al. Clin Pharmacokinet. 2017;56(4):339–354.

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شرکت نوو نورددیسک پارس: تهران، خیابان ولیعصر، خیابان ناصری، ساختمان کیان،  
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**RYZODEG®**

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