Uncontrolled diabetes and excess weight

worsens the outcomes

89 %

PwD live with excess weight[1]

49 %

PwD live with CHD[2]

77 %

PwD live with poor glycaemic control[1]

This is a model and not a real patient

Abbreviations: CHD, Coronary heart disease | PwD People with diabetes

Reference:1 Borgharkar SS,BMJ Open Diabetes Res Care. 2019 Jul 14;7(1):e000654. | 2. Eeg-Olofsson K et al. Diabetologia. 2009 Jan;52(1):65-73.

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Let's Lower

#WeightofDiabetes

with

[3]

- $HbA1_c$ Reduction
- Weight Reduction
- Consistent CV safety

CV - Cardiovascular HbA1c: Glycated hemoglobin

3. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan 1;47(Suppl 1):S158-S178

Let's Lower

#WeightofDiabetes

with 3 in 1[3]

FOR PEOPLE WITH UNCONTROLLED TYPE 2 DIABETES

RYBELSUS®

semaglutide tablets

A GAME CHANGER. A LIFE CHANGER.

Unprecedented HbA1c reduction

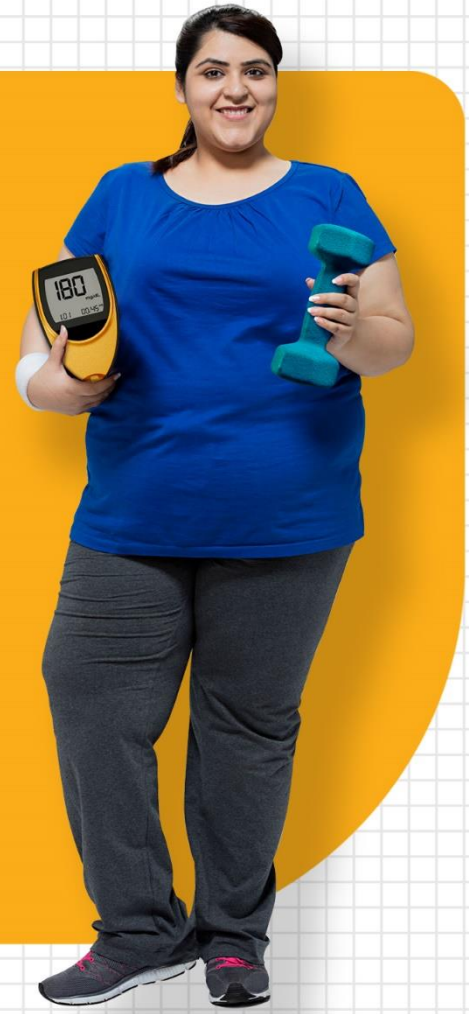
2.6%

in individuals with baseline $HbA1_c$ >9%[4]

Up to

1.5

reduction in $HbA1_c$[$,4]



This is a model and not a real patient

References: $ Baseline HBA1c – 8.0%

Abbreviations: HbA1c: Glycated hemoglobin

4. Aroda VR, et al. Diabetes Obes Metab. 2022 Jul;24(7):1338-1350.

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#WeightofDiabetes

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Unsurpassed weight loss

4.7 cm

reduction in waist circumference[#,^,5]

Up to

5 kg

weight loss[6,7]

This is a model and not a real patient

References: #Baseline waist circumference: 104.5 cm ^Estimated treatment dierence between Oral semaglutide 14mg (-4.2 cm) compared with placebo (+0.5 cm).

5. Zinman B, et al. Diabetes Care. 2019 Dec;42(12):2262-2271. | 6 Baseline weight - 92.9 kg 7. Pratley R, et al. Lancet. 2019;94(10192):39-50.

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#WeightofDiabetes

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Consistent CV safety

49% risk reduction for all causes of death[8]

21% MACE reduction® [9]

This is a model and not a real patient

Abbreviation: CV - Cardio Vascular MACE - Major adverse cardiovascular events References: 8. Data expressed in terms of relative risk reduction with oral semaglutide 14 mg compared with placebo. Results were non-significant for the primary outcome of MACE reduction Hazards Ratio 0.51 (95% CI, 0.31–0.84). Husain M et al. N Engl J Med 2019;381:841–51

9. Husain M et al. N Engl J Med 2019;381:841–51 Hazards Ratio 0.79 (95% CI, 0.57–1.11)

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#WeightofDiabetes

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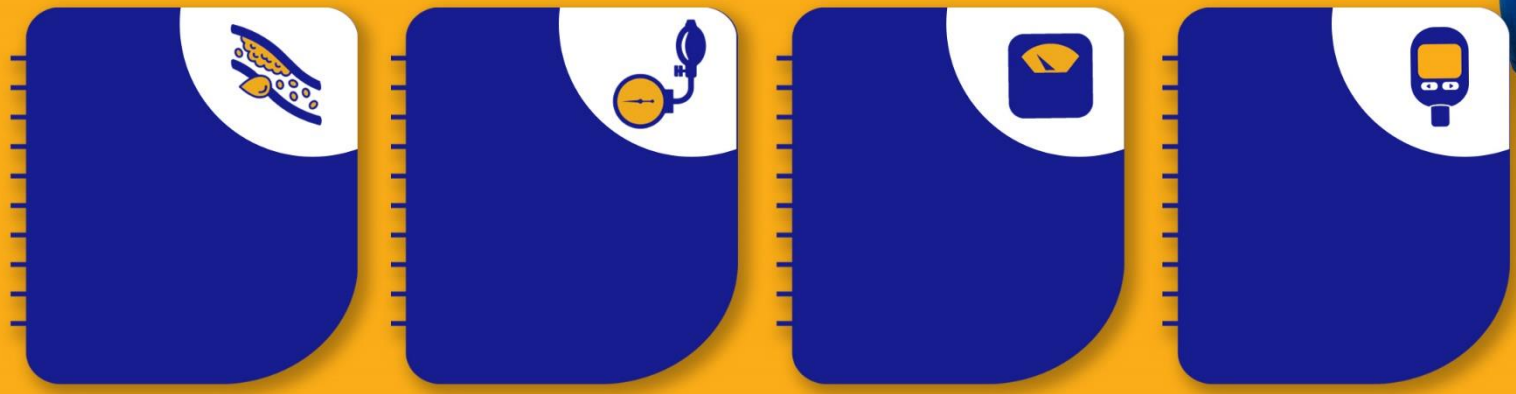
FOR PEOPLE WITH UNCONTROLLED TYPE 2 DIABETES

RYBELSUS®

semaglutide tablets

A GAME CHANGER. A LIFE CHANGER.

Reduction of multiple cardio-metabolic risk factors



This is a model and not a real patient. Abbreviations: HbA1c: Glycated hemoglobin, TC: Total cholesterol, G: Triglycerides, LDL: low-density lipoprotein

References: $Baseline HbA1c – 8.0% 10. non-significant, $Baseline waist circumference – 104.5 cm, 11. Dahl K et al. Diabetes Obes Metab. 2021 Jul;23(7):1594-1603. 12.Baseline SBP – 135 mmHg, 13. Husain M et al. N Engl J Med 2019;381:841–51. 14.Baseline weight – 92.9 kg, +Baseline HbA1c – 8.0% 15. Pratley R, et al. Lancet. 2019;94(10192):39-50. 16. Aroda VR et al. Diabetes Care. 2019 Sep;42(9):1724-1732.

Let's Lower

#WeightofDiabetes

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RYBELSUS®

semaglutide tablets

A GAME CHANGER. A LIFE CHANGER.

Reduction of multiple cardio-metabolic risk factors

Lipid Profile

LDL, TC, TG[10,11]

Systolic blood pressure

-5mm Hg[12,13]

Weight

-5kg[14,15]

HbA1c (%)

-1.5%+,[16]

This is a model and not a real patient. Abbreviations: HbA1c: Glycated hemoglobin, TC: Total cholesterol, G: Triglycerides, LDL: low-density lipoprotein

References: $Baseline HbA1c – 8.0% 10. non-significant, $Baseline waist circumference – 104.5 cm, 11. Dahl K et al. Diabetes Obes Metab. 2021 Jul;23(7):1594-1603. 12.Baseline SBP – 135 mmHg, 13. Husain M et al. N Engl J Med 2019;381:841–51. 14.Baseline weight – 92.9 kg, +Baseline HbA1c – 8.0% 15. Pratley R, et al. Lancet. 2019;94(10192):39-50. 16. Aroda VR et al. Diabetes Care. 2019 Sep;42(9):1724-1732.

Treat today's disease to prevent tomorrow's complications[3]

Let's Lower

#WeightofDiabetes

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Ref.: 3 Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan 1;47(Suppl 1):S158-S178

Abbreviated prescribing information (and not full package insert)
Generic Name: Semaglutide Tablets
Brand Name: Rybelsus® 3 mg tablets, Rybelsus® 7 mg tablets and Rybelsus®14 mg tablets.
Presentation: Rybelsus® 3 mg, 7 mg and 14 mg tablets for once-daily oral use. Each tablet contains 3, 7 or 14 mg semaglutide. Tablet for once daily oral use. **Indication:** Semaglutide is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications. • in combination with other medicinal products for the treatment of diabetes. **Description:** The semaglutide drug products are white to light yellow oval shaped tablets. The primary packaging is a blister card composed of coloured forming foil and non-coloured lid foil. The colour of the forming foil is unique for each tablet strength: green for 3 mg tablets, red for 7 mg tablets and blue for 14 mg tablets. The blister card contains 10 identical cavities, each containing 1 tablet. Batch specific information is printed on each blister card. The secondary packaging consists of an outer sales carton. **Dosing and administration: Posology** The starting dose of Rybelsus® is 3 mg once daily. After 1 month, the dose should be increased to a maintenance dose of 7 mg once daily. If additional benefits are needed after at least one month on the 7 mg dose, the dose can be increased to a maintenance dose of 14 mg once daily. Rybelsus® can be used as monotherapy or in combination with one or more glucose-lowering medicinal products. When Rybelsus® is used in combination with metformin and/or a sodium-glucose co-transporter 2 inhibitor (SGLT2i) or thiazolidinedione, the current dose of metformin and/or SGLT2i/thiazolidinedione can be continued. When Rybelsus® is used in combination with a sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia. **Missed dose:** If a dose is missed, the missed dose should be skipped, and the next dose should be taken the following day. **Method of administration:** Rybelsus® is a tablet for once-daily oral use. Rybelsus® should be taken on an empty stomach. Rybelsus® should be swallowed whole with up to half a glass of water equivalent to 120 ml. Do not split, crush or chew the tablet. Wait at least 30 minutes before the first meal or drink of the day or taking other oral medicinal products. Waiting less than 30 minutes may decrease the absorption of semaglutide. **Special Population:** Elderly (_65 years old): No dose adjustment is required based on age. Gender: No dose adjustment is required based on gender. Race and ethnicity: No dose adjustment is required based on race and ethnicity. Patients with hepatic impairment: No dose adjustment is required for patients with hepatic impairment. Patients with renal impairment: No dose adjustment is required for patients with renal impairment. Children and adolescents: The safety and efficacy of Rybelsus® in children and adolescents below 18 years have not been studied. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions:** Rybelsus® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Gastrointestinal effects: Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions that can cause dehydration, which in rare cases can lead to a deterioration of renal function. Acute pancreatitis: Acute pancreatitis has been observed with the use of GLP-1 receptor agonists. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, Rybelsus® should be discontinued; if confirmed, Rybelsus® should not be restarted. Caution should be exercised in patients with a history of pancreatitis. In the absence of other signs and symptoms of acute pancreatitis, elevations in pancreatic enzymes alone are not predictive of acute pancreatitis. Hypoglycaemia: Insulin and sulfonylurea are known to cause hypoglycaemia. Patients treated with Rybelsus® in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia can be lowered by reducing the dose of sulfonylurea or insulin when initiating treatment with Rybelsus®. Diabetic retinopathy: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Long-term glycaemic control decreases the risk of diabetic retinopathy. Patients with a history of diabetic retinopathy should be monitored for worsening and treated according to clinical guidelines. Heart failure: There is no therapeutic experience in patients with congestive heart failure New York Heart Association (NYHA) class IV. **Pregnancy and lactation:** Studies in animals have shown reproductive toxicity. There are limited data from the use of semaglutide in pregnant women. Therefore, Rybelsus® should not be used during pregnancy. Women of childbearing potential are recommended to use contraception when treated with Rybelsus®. If a patient wishes to become pregnant, or pregnancy occurs, Rybelsus® should be discontinued. Rybelsus® should be discontinued at least 2 months before a planned pregnancy due to the long half-life. In lactating rats, semaglutide, salcaprozate sodium and/or its metabolites were excreted in milk. As a risk to a breast-fed child cannot be excluded, Rybelsus® should not be used during breast-feeding. **Impact on semaglutide on the exposure of co-administered oral medicinal products:** Interaction with other medicines: In vitro studies have shown very low potential for semaglutide to inhibit or induce CYP enzymes, and to inhibit drug transporters. Semaglutide delays gastric emptying which may influence the absorption of other oral medicinal products. No clinically relevant drug-drug interaction with semaglutide was observed based on the evaluated medicinal products. Therefore, no dose adjustment is required for medicinal products when taken with Rybelsus®. Effects of Rybelsus® on other medicinal products: Total exposure (AUC) of thyroxine (adjusted for endogenous levels) was increased by 33% following administration of a single dose of levothyroxine. Maximum exposure (Cmax) was unchanged. Monitoring of thyroid parameters should be considered when treating patients with semaglutide at the same time as levothyroxine. No clinically relevant change in AUC or Cmax of warfarin, digoxin, oral contraceptives (containing ethinylestradiol and levonorgestrel), metformin, furosemide or rosuvastatin was observed when concurrently administered with semaglutide. Effects of other medicinal products on semaglutide: No clinically relevant change in AUC or Cmax of semaglutide was observed when taken with omeprazole. Interaction with food: Concomitant intake of food reduces the exposure of semaglutide. **Undesirable Effects:** In 10 phase 3a trials, 5,707 patients were exposed to Rybelsus® alone or in combination with other glucose-lowering medicinal products. The duration of the treatment ranged from 26 weeks to 78 weeks. The most frequently reported adverse reactions in clinical trials were gastrointestinal disorders, including nausea, diarrhoea and vomiting. In general, these reactions were mild or moderate in severity and of short duration. **Shelf life:** 3 mg: 24 months; 7 mg: 30 months; 14 mg: 30 months. **Storage** Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month. Do not store above 30°C. Store in the original package to protect from moisture and light. Keep the tablet in the blister until you are ready to take it. Removing it too soon can prevent it from working as planned. Do not use this medicine if you notice that the package is damaged or shows signs of being open.
Disclaimer: The abbreviated package insert is updated from the CDSCO approved package insert version dated 18 Aug 2021. Rybelsus® is a registered trademark owned by Novo Nordisk A/S and registered in Denmark. Imported by: Novo Nordisk India Private Limited, Bangalore
*The full prescribing information can be obtained at no cost from Novo Nordisk. For full prescribing information please contact +91-080-40303200 or write to us at INAgree@novonordisk.com or reach us at Novo Nordisk India Private Limited NXT Tower -2, Floor 1 & 2 Embassy Manyata Business Park, Nagavara Village, Kasaba Hobli, Bangalore-560045.
Note: For detailed information on this product, please refer to full package insert*.
 Please refer latest summary of product characteristics for more details. To get information on the updated package insert please contact +91 80 4030 3200 or write to us at inagree@novonordisk.com.
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