

The World's First and Only Oral GLP-1 RA

RYBELSUS[®]

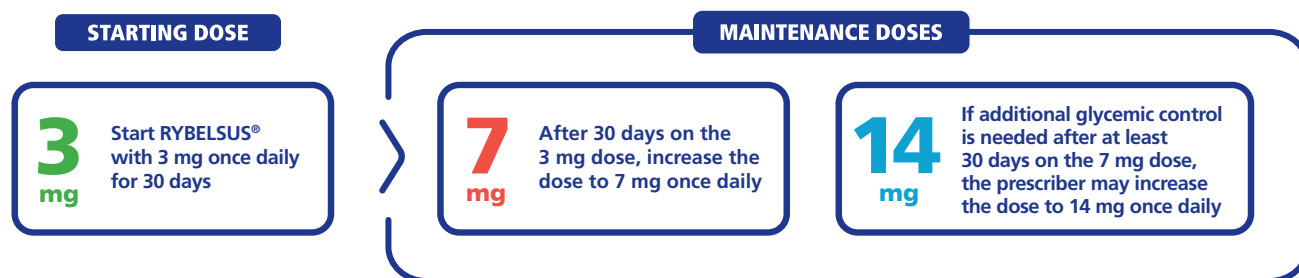
semaglutide tablets 7mg | 14mg

RYBELSUS[®] (semaglutide) tablets 7 mg or 14 mg is a once-daily pill indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes¹



	RYBELSUS [®] 3 mg pack	RYBELSUS [®] 7 mg pack	RYBELSUS [®] 14 mg pack
NDC	0169-4303-13	0169-4307-13	0169-4314-13
Box quantity	30 x 3 mg per box	30 x 7 mg per box	30 x 14 mg per box

Start Patients on RYBELSUS[®] with 3 mg Once Daily for 30 Days, then Increase Dose¹



- 3 mg is intended for initiation and is not effective for glycemic control
- Gradual dose escalation is designed to help patients adjust to therapy

If a patient misses a dose, the missed dose should be skipped, and the next dose should be taken the following day.

Indications and Usage

RYBELSUS[®] (semaglutide) tablets 7 mg or 14 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Limitations of Use

- RYBELSUS[®] is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans
- RYBELSUS[®] has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis
- RYBELSUS[®] is not indicated for use in patients with type 1 diabetes or for the treatment of patients with diabetic ketoacidosis

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether RYBELSUS[®] causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined
- RYBELSUS[®] is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of RYBELSUS[®] and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with RYBELSUS[®]

Contraindications

- RYBELSUS[®] is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), and in patients with known hypersensitivity to semaglutide or to any of the components in RYBELSUS[®]



GLP-1 RA=Glucagon-like peptide-1 receptor agonist.

Please see additional Important Safety Information on next page. Please click on paper clip icon for Prescribing Information, including Boxed Warning.



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Instructions for Patients For once-daily RYBELSUS® to work as planned, patients should take as directed.

Taking RYBELSUS®



Patients should take RYBELSUS® on an empty stomach when they first wake up, at least 30 minutes before the first food, beverage, or other oral medications of the day.



RYBELSUS® should be taken with a sip of plain water (no more than 4 ounces). Swallow tablet whole. Do not cut, crush, or chew.



RYBELSUS® works best if patients eat 30-60 minutes after taking Rybelsus.

Storage and Handling



Store at room temperature
68°F – 77°F.

Keep tablet in the blister pack in a dry place away from moisture until you are ready to take it. Push tablet out of blister. Do not cut from the packaging.

Saving on RYBELSUS®

Eligible patients may pay as little as \$10 for a 30-day prescription

To qualify, commercial insurance coverage is required. Eligibility and other restrictions apply. Visit **Rybelsus.com** for full program details and eligibility requirements.

The RYBELSUS® Savings Offer is digital only. Patients can get the offer by texting **READY** to 21848 or download the savings offer at **SaveOnR.com**

Patient Support



Text messaging

Text* **READY** to 21848 to get started.



One-on-One, Live Support

Call **1-833-ASK-A-CDE** Monday through Friday, 9:00 AM – 6:00 PM ET.

*Message and data rates may apply. Check with mobile service provider. See Terms of Use & Conditions at Rybelsus.com.

Direct patients to read their packaging or visit Rybelsus.com for more detailed information.

Pharmacy Connect Information

If you have any issue processing the offer, please call **1-888-401-0112** to speak directly with a member of our Pharmacy Connect team.

Hours of operation: Monday – Friday, 8:00 AM – 8:00 PM ET (except holidays)

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- Risk of Thyroid C-Cell Tumors:** Patients should be further evaluated if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging
- Pancreatitis:** Has been reported in clinical trials. Observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue RYBELSUS® and initiate appropriate management; if confirmed, do not restart RYBELSUS®
- Diabetic Retinopathy Complications:** In a pooled analysis of glycemic control trials with RYBELSUS®, patients reported diabetic retinopathy related adverse reactions during the trial (4.2% with RYBELSUS® and 3.8% with comparator). In a 2-year trial with semaglutide injection involving patients with type 2 diabetes and high cardiovascular risk, more events of diabetic retinopathy complications occurred in patients treated with semaglutide injection (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline than among patients without a known history of diabetic retinopathy. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy
- Hypoglycemia:** The risk of hypoglycemia is increased when RYBELSUS® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Patients may require a lower dose of the secretagogue or insulin to reduce the risk of hypoglycemia in this setting
- Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists, including semaglutide. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of RYBELSUS® in patients reporting severe adverse gastrointestinal reactions
- Hypersensitivity:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists, including

semaglutide. If hypersensitivity reactions occur, discontinue use of RYBELSUS®, treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist

Adverse Reactions

- The most common adverse reactions, reported in ≥5% of patients treated with RYBELSUS® are nausea, abdominal pain, diarrhea, decreased appetite, vomiting and constipation

Drug Interactions

- The risk of hypoglycemia may be lowered by a reduction in the dose of concomitantly administered secretagogues or insulin
- RYBELSUS® delays gastric emptying and has the potential to impact the absorption of other oral medications. Closely follow RYBELSUS® administration instructions when coadministering with other oral medications and consider increased monitoring for medications with a narrow therapeutic index, such as levothyroxine

Use in Specific Populations

- Pregnancy:** Available data with RYBELSUS® are not sufficient to determine a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to RYBELSUS®. Use only if the potential benefit justifies the potential risk to the fetus
- Lactation:** There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the unknown potential for serious adverse reactions in the breastfed infant due to the possible accumulation of salcaprozate sodium (SNAC), an absorption enhancer in RYBELSUS®, from breastfeeding and because there are alternative formulations of semaglutide that can be used during lactation, advise patients that breastfeeding is not recommended during treatment with RYBELSUS®
- Discontinue RYBELSUS® in women at least 2 months before a planned pregnancy due to the long washout period for semaglutide
- Pediatric Use:** Safety and efficacy of RYBELSUS® have not been established in pediatric patients (younger than 18 years)

Please see additional Important Safety Information on previous page. Please click on paper clip icon for Prescribing Information, including Boxed Warning.

To learn more about RYBELSUS®, visit RybelsusPro.com or call 1-833-457-7455



Reference: 1. RYBELSUS® package insert. Plainsboro, NJ: Novo Nordisk Inc; January 2020.

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