For adults with type 2 diabetes

**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®.

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**RYBELSUS® IS A ONCE-DAILY ORAL TABLET THAT MUST BE TAKEN**:

- On an empty stomach when the patient first wakes up.
- With a sip of plain water (no more than 4 oz).
- At least 30 minutes before the first food, beverage, or other oral medications of the day.

- Waiting less than 30 minutes, or taking with food, beverages (other than plain water), or other oral medications will lessen the effect of RYBELSUS® by decreasing its absorption.
- Waiting more than 30 minutes to eat may increase the absorption of RYBELSUS®.

Advise patients to swallow whole and not split, crush, or chew tablets. If they miss a dose, it should be skipped—and their next dose should be taken the following day.

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

Please see Important Safety Information throughout, and accompanying Prescribing Information, including Boxed Warning.
## Important Safety Information

### 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®.

### 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
- **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®.

#### Pediatric Use:
- Safety and efficacy of RYBELSUS® have not been established in pediatric patients (younger than 18 years).

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### Trade Pack | Strength | NDC Number | Dosage Form | SIG | Notes to Pharmacy | Dispense Quantity
---|---|---|---|---|---|---
Starter dose | 3 mg | 00169-4303-13 | Tablet | One pill daily on an empty stomach with up to 4 oz plain water. Swallow whole. Wait 30 min to eat, drink, or take other oral meds. | One pill daily on an empty stomach with up to 4 oz plain water. Swallow whole. Do not cut, crush, or chew. Wait 30 min to eat, drink, or take other oral meds. | 30 tablets
Maintenance dose | 7 mg | 00169-4307-13 | Tablet | One pill daily on an empty stomach with up to 4 oz plain water. Swallow whole. Wait 30 min to eat, drink, or take other oral meds. | One pill daily on an empty stomach with up to 4 oz plain water. Swallow whole. Do not cut, crush, or chew. Wait 30 min to eat, drink, or take other oral meds. | 30 tablets
Maintenance dose | 14 mg | 00169-4314-13 | Tablet | One pill daily on an empty stomach with up to 4 oz plain water. Swallow whole. Wait 30 min to eat, drink, or take other oral meds. | One pill daily on an empty stomach with up to 4 oz plain water. Swallow whole. Do not cut, crush, or chew. Wait 30 min to eat, drink, or take other oral meds. | 30 tablets
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Please see Important Safety Information throughout, and accompanying Prescribing Information, including Boxed Warning.

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

Advise patients to swallow whole and not split, crush, or chew tablets. If they miss a dose, it should be skipped—and their next dose should be taken the following day.

It is recommended that RYBELSUS® be taken in the morning on an empty stomach when the patient first wakes up.

Waiting less than 30 minutes, or taking with food, beverages (other than plain water), or other oral medications will lessen the effect of RYBELSUS® by decreasing its absorption.

Waiting more than 30 minutes to eat may increase the absorption of RYBELSUS®. Take with a sip of plain water (no more than 4 oz) at least 30 minutes before the first food, beverage, or other oral medications of the day.

RYBELSUS® is a registered trademark of Novo Nordisk A/S.

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THE WORLD’S FIRST AND ONLY ORAL GLP-1 RA

For adults with type 2 diabetes to improve glycemic control

START PATIENTS ON RYBELSUS® WITH 3 mg ONCE DAILY FOR 30 DAYS, THEN INCREASE THE DOSE

STARTING DOSE

3 mg

Start RYBELSUS® with 3 mg once daily for 30 days

MAINTENANCE DOSES

7 mg

After 30 days on the 3 mg dose, increase the dose to 7 mg once daily

14 mg

If additional glycemic control is needed after at least 30 days on the 7 mg dose, the dose can be increased to 14 mg once daily

• The 3 mg dose is intended for initiation and is not effective for glycemic control

• Gradual dose escalation is designed to help patients adjust to their therapy

Please see Important Safety Information throughout, and accompanying Prescribing Information, including Boxed Warning.


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