

Helpful tips to keep in mind before your call



Keep this **reference guide** and other RYBELSUS® materials from sales representatives handy as resources to refer to during your virtual vict.



Before hanging up, go over next steps, such as scheduling a follow-up, what information patients should take with them to the pharmacy (such as their savings offer, if eligible), or picking up their RYBELSUS® script

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

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[®]







3 important things to cover about dosing and administration with RYBELSUS®



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 a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in RYBELSUS®. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with 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®







Getting patients started on RYBELSUS[®] virtually

3 important things to cover about dosing and administration with RYBELSUS®



Important Safety Information

- 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 in patients treated with RYBELSUS®. 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







Getting patients started on RYBELSUS[®] virtually



Go over the following storage instructions with your patients they must follow these so that RYBELSUS® works as planned¹:



Store tablets in the closed RYBELSUS® bottle until ready to take one



Do not use a pill organizer or other container to store RYBELSUS® tablets



Swallow tablet whole. Do not cut, crush, or chew them

Important Note: The RYBELSUS® blue cap is equipped with a drying agent to help protect the tablets from moisture, which helps preserve RYBELSUS®. Tablets should be kept in the RYBELSUS® bottle with the blue cap on whenever the patient is not taking one.

Store at room temperature $68^{\circ}F-77^{\circ}F$ ($20^{\circ}C-25^{\circ}C$). Store in a dry place away from moisture.

Important Safety Information

Drug Interactions

- When initiating RYBELSUS®, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia
- 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







Provide your patients with video links to view on their own time



To learn more about starting RYBELSUS[®],

let your patients know they can visit:

<u>RYBELSUS.com</u> Why RYBELSUS[®]? RYBELSUS[®] Videos

Important Safety Information

Warnings and Precautions

- 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 semaglutidie 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. 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: Patients receiving RYBELSUS® in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia





If your patients have commercial insurance, they could be eligible for the RYBELSUS[®] savings offer^a

3 ways patients can enroll:



*For commercially insured patients only. Eligibility and other restrictions apply. *Message and data rates may apply. Check with your mobile service provider. See Terms and Conditions of Use at RYBELSUS.com.

Important Safety Information

Use in Specific Populations

- 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 $^{\circ}$ 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 Important Safety Information throughout. Please see Prescribing Information, including Boxed Warning, at <u>RYBELSUSpro.com</u>.

Reference: 1. RYBELSUS® [package insert]. Plainsboro, NJ: Novo Nordisk Inc; April 2021.



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