EHR Best Practices: Accurately ePrescribing RYBELSUS®

RYBELSUS® semaglutide tablets 7mg | 14mg

Please consider the information below to accurately ePrescribe RYBELSUS® for appropriate patients:

Product Name	Strength	NDC Number	Dose Escalation	SIG	Notes to Pharmacy
RYBELSUS® (semaglutide) 3 mg tablet (Starter Dose)	3 mg	00169-4303-13	Start RYBELSUS® with 3 mg once daily for 30 days*	One pill daily on an empty stomach with up to 4 oz of 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 of plain water. Swallow whole. Do not cut, crush, or chew. Wait at least 30 min to eat, drink, or take other oral meds
RYBELSUS® (semaglutide) 7 mg tablet (Maintenance Dose)	7 mg	00169-4307-13	After 30 days on the 3 mg dose, increase the dose to 7 mg once daily	One pill daily on an empty stomach with up to 4 oz of 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 of plain water. Swallow whole. Do not cut, crush, or chew. Wait at least 30 min to eat, drink, or take other oral meds
RYBELSUS® (semaglutide) 14 mg tablet (Maintenance Dose)	14 mg	00169-4314-13	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	One pill daily on an empty stomach with up to 4 oz of 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 of plain water. Swallow whole. Do not cut, crush, or chew. Wait at least 30 min to eat, drink, or take other oral meds

Samples should be captured within the EHR—all EHRs have a place to document when a sample has been provided so the medication is captured in the patient's medication list.

For EHRs that have drop-down options for the SIG, the HCPs may be able to change to a free text option or should add additional patient instructions in the Notes to Pharmacy field.

*The 3 mg dose is intended for initiation (starting dose) and is not effective for glycemic control. It is essential that patients start at the 3 mg dose based on the dose escalation schedule.

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®**

Indication 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® 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

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®

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If you have chosen to prescribe RYBELSUS® and it is not available in your EHR, consider consulting with your practice's EHR IT support team to manually add RYBELSUS® to the product list. Manually adding RYBELSUS® will enable documentation of a sample or prescription in the EHR for future reference.

PLEASE NOTE:

Manually added medications are not validated for drug interactions, drug allergies, duplicate therapies, or other potential adverse drug events or formulary compliance.

General instructions to manually add a medication to an EHR

Contact your practice's EHR IT support team to confirm that your EHR and health system or practice permits manually-added products in the EHR

- Some health systems may limit this capability to select users with specific IT privileges

If your EHR does not offer the capability to manually add RYBELSUS®, you may be able to write a one-time prescription

- RYBELSUS® will not be added to the product list and won't appear in the drug search
- The prescription may not be transmitted electronically to a pharmacy
- These prescriptions may be printed in the office and given to the patient to take to the pharmacy or phoned in to the pharmacy

Visit the RYBELSUS® website at RYBELSUSpro.com to view EHR best practices for accurately ePrescribing RYBELSUS®

Once your EHR or health system has updated the EHR product list to include RYBELSUS®, delete your manually added product listing to avoid duplication

If you have additional RYBELSUS® product-related questions, please contact Novo Nordisk Medical Information: 1-833-457-7455 or NovoNordiskMedical.com.

Important Safety Information

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:** Patients receiving RYBELSUS® in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia
- **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

Please see additional Important Safety Information throughout and click here for Prescribing Information, including Boxed Warning.

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Important Safety Information

Warnings & Precautions (cont'd)

- **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
- **Acute Gallbladder Disease:** Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing. In placebo-controlled trials, cholelithiasis was reported in 1% of patients treated with RYBELSUS® 7 mg. Cholelithiasis was not reported in RYBELSUS® 14 mg or placebo-treated patients. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated

Adverse Reactions

- Most common adverse reactions (incidence ≥5%) are nausea, abdominal pain, diarrhea, decreased appetite, vomiting and constipation

Drug Interactions

- RYBELSUS® stimulates insulin release in the presence of elevated blood glucose concentrations. 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
- **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 effectiveness of RYBELSUS® have not been established in pediatric patients

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