Rybelsus (semaglutide)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Rybelsus
- **Generic name:** Semaglutide
- **Pharmacologic class:** Glucagon-like peptide-1 (GLP-1) receptor agonist
- **Strength and Formulation:** 3mg, 7mg, 14mg; tablets
- **Manufacturer:** Novo Nordisk
- **How supplied:** Blister packs—30 tablets
- **Legal Classification:** Rx

Rybelsus


NDC 0169-4303-13
List 430313
RYBELSUS®
3 mg
(semaglutide) Tablets
3 mg
Once daily
Each tablet contains 3 mg semaglutide
Oral use only
Rx only
Dispense the Enclosed Medication Guide to Each Patient
30 tablets
3 blister packs. Each pack contains 10 tablets.
novo nordisk®
Open Here
7 mg
14 mg

Indication

- Adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**

Limitations of Use

- **Not recommended** as first-line therapy for patients inadequately controlled on diet and exercise
- **Not studied** with a history of pancreatitis
- **Not for treating** type 1 diabetes or diabetic ketoacidosis

Dosage and Administration

- <18yrs: not established
- ≥**18yrs**: Take at least 30mins before first food, beverage, or other oral medications with max 4oz of plain water only
- Initially 3mg once daily for 30 days, then increase to 7mg once daily; may increase to 14mg once daily if additional glycemic control needed after ≥30 days on 7mg dose
- Taking two 7mg tablets to achieve a 14mg dose is **not recommended**

Dosage and Administration

- *Switching between semaglutide subcutaneous (SC) injection (Ozempic) and oral semaglutide (Rybelsus)*
  - Patients treated with Rybelsus 14mg daily can be transitioned to Ozempic 0.5mg once weekly
  - Patients can start Ozempic the day after last dose of Rybelsus
  - Patients treated with once weekly Ozempic 0.5mg can be transitioned to Rybelsus 7mg or 14mg
  - Patients can start Rybelsus up to 7 days after their last injection of Ozempic
  - There is no equivalent dose of Rybelsus for Ozempic 1mg

Considerations for Special Populations

- **Pregnancy:** data insufficient to evaluate risk; should only be used if benefit outweighs potential risk
  - Discontinue at least 2 months before planned pregnancy due to long washout period
- **Nursing mothers**: breastfeeding *not recommended* during treatment
- **Pediatric**: safety and efficacy not established in patients <18yrs of age
- **Geriatric:** no overall differences detected between younger patients and those ≥65yrs
- **Renal impairment**: no dose adjustment recommended
- **Hepatic impairment**: no dose adjustment recommended

Contraindications

- History (personal or family) of medullary thyroid carcinoma
- Multiple endocrine neoplasia syndrome type 2

Warnings and Precautions

- Risk of **thyroid C-cell tumors**; inform patients of potential risk and symptoms
- History of **pancreatitis**; consider other antidiabetics
- Monitor for pancreatitis; discontinue if suspected; do not restart if confirmed
- History of **diabetic retinopathy**; monitor for progression
- Monitor renal function when initiating or escalating dose in patients reporting severe adverse gastrointestinal reactions
- History of anaphylaxis or angioedema with other GLP-1 receptor agonist
- Discontinue if hypersensitivity reactions occur

Interactions

- Increased risk of **hypoglycemia** with concomitant insulin secretagogues (eg, sulfonylureas) or insulin; may need lower dose of these
- May affect absorption of concomitant oral drugs (**delayed gastric emptying**); caution

Adverse Reactions

- **Most common (incidence >5%)**: nausea, abdominal pain, diarrhea, decreased appetite, vomiting, constipation
- **Others** (rare): pancreatitis, hypersensitivity reactions

Mechanism of Action

- Semaglutide acts as a **GLP-1 receptor agonist** that selectively binds to and activates the GLP-1 receptor
- It reduces blood glucose by stimulating insulin secretion and lowering glucagon secretion in a glucose-dependent manner

Pharmacokinetics

- **Absorption:** max concentration reached 1 hour post-dose; steady-state exposure achieved following 4-5 weeks administration
- **Protein binding**: >99%
- **Elimination**: half-life ~1 week; present in circulation for about 5 weeks after last dose
- **Metabolism**: primary route of elimination is metabolism following proteolytic cleavage of the peptide backbone and sequential beta-oxidation of the fatty acid side chain
- **Excretion**: primary excretion routes via urine and feces

Clinical Trials

- Rybelsus has been studied as monotherapy and in combination with metformin, sulfonylureas, sodium-glucose co-transporter (SGLT-2) inhibitors, insulins, and thiazolidinediones in patients with type 2 diabetes
- Its efficacy was compared with placebo, empagliflozin, sitagliptin, and liraglutide

Clinical Trials

- A 26-week double-blind trial (N=703) randomized patients to Rybelsus 3mg, 7mg or 14mg once daily or **placebo**
- Results showed a statistically significant reduction in HbA1c with Rybelsus 7mg and 14mg vs placebo (−1.2% and −1.4% vs −0.3%, respectively)

Clinical Trials

- In a 26-week open-label trial (N=822), patients with type 2 diabetes were randomized to Rybelsus 14mg once daily or **empagliflozin** 25mg once daily, all in combination with metformin

- Results showed a statistically significant reduction in HbA1c with Rybelsus 14mg vs empagliflozin 25mg (−1.3% vs −0.9%, respectively)

Clinical Trials

- A 26-week double-blind trial (N=1864) randomized patients with type 2 diabetes to Rybelsus 3mg, 7mg, 14mg once daily or **sitagliptin** 100mg once daily, all in combination with metformin ± sulfonylurea

- Results showed a statistically significant reduction in HbA1c with Rybelsus 7mg and 14mg vs sitagliptin 100mg (−1.0% and −1.3% vs −0.8%, respectively)

Clinical Trials

- A 26-week, double-blind, double-dummy trial (N=711) randomized patients with type 2 diabetes on metformin ± SGLT-2 inhibitors to Rybelsus 14mg once daily, **liraglutide** 1.8mg subcutaneous injection once daily, or placebo
- Results showed a statistically significant reduction in HbA1c with Rybelsus 14mg vs placebo (−1.2% vs −0.2%)
- Rybelsus 14mg demonstrated non-inferior reductions in HbA1c vs liraglutide (−1.2% vs −1.1%)

Clinical Trials

- A 26-week double-blind trial (N=731) randomized patients **inadequately controlled on insulin** (basal, basal/bolus or premixed) ± metformin to Rybelsus 3mg, 7mg, 14mg once daily or placebo
- Results showed statistically significant reductions in HbA1c with Rybelsus 7mg and 14mg vs placebo (−0.9% and −1.3% vs −0.1%, respectively)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/rybelsus/