

## FDA Adds Warning to Ozempic, Caution Advised for Similar Drugs

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Semaglutide is the active ingredient in medications marketed as Ozempic, Wegovy, Rybelsus. All of these drugs are injectable GLP-1 receptor agonist medications indicated for type 2 diabetes, but their popularity in the general population as a weight-loss drug is skyrocketing.

PWCF is beginning to hear from a few families that their doctors are prescribing to their loved one with PWS Ozempic, Wegovy, Rybelsus, or Mounjaro (active ingredient tirzepatide), or Saxenda (active ingredient liraglutide which has the pediatric indication and the same side effect profile) in attempt to reduce the PWS hyperphagia appetite. While some families have reported these medications do indeed seem to reduce appetite in their loved one, we have consistently advised caution and very close monitoring for the potential for increased constipation.

We now know that **both drugs can also cause gastroparesis**, a delay of the stomach emptying process in which normal contraction of the stomach muscles is slow or even stops. Drug labels for semaglutide, tirzepatide, and liraglutide mention "delay of gastric emptying" under potential drug interactions, but not under warnings or adverse events.

Sophie Pulka reported in *MedPage News* (September 28, 2023) that "Labeling for semaglutide 2.4 mg (Wegovy) -- indicated for obesity -- already reflects the potential adverse reaction based on postmarketing reports" and notes that **gastrointestinal disorders** can include "**acute pancreatitis** and **necrotizing pancreatitis**, sometimes resulting in death, **ileus**" and that that "labeling for tirzepatide (Mounjaro), a dual GIP/GLP-1 receptor agonist approved for type 2 diabetes, was changed to add ileus as a potential side effect based on postmarketing reports in July."

Ileus can cause cramping and pain, the inability to have a bowel movement, swelling, vomiting, or lack of appetite, according to the Mayo Clinic, and often leads to hospitalization to first stabilize the condition, followed by a barium or air enema or, for complete intestinal obstruction, surgery.

Because slow stomach emptying (gastroparesis) and slow bowel emptying are already common symptoms in PWS, **use of drugs that contain the active ingredient semaglutide, tirzepatide, or liraglutide should be used with extreme caution and frequent monitoring especially in patients diagnosed with PWS.**