

Drug Safety Communication Sample

FDA label-based adverse event translation | semaglutide

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Sample Type: Drug safety and adverse event plain-language table

Scenario: A medical communications team needs a balanced, source-grounded safety summary for semaglutide injection in adults with type 2 diabetes. The sample demonstrates how to translate label-based adverse reaction information into plain language while preserving clinical meaning and avoiding promotional framing.

Safety communication principles

- Use the approved label as the controlling source for product-specific safety language.
- Separate common adverse reactions from warnings, precautions, and symptoms requiring medical attention.
- Avoid implying that percentages from clinical trials predict an individual patient outcome.
- Use plain language definitions while preserving medical terms in parentheses when useful.

Plain-language adverse event table

Medical term	Plain-language description	Communication note
Nausea	Feeling sick to your stomach or feeling like you may throw up.	Commonly reported in trials; often important to mention early in patient education.
Vomiting	Throwing up.	May contribute to dehydration if persistent or severe.
Diarrhea	Loose or watery stools.	Discuss hydration and when to contact a clinician.
Abdominal pain	Pain or discomfort in the stomach area.	Needs context because abdominal pain can be mild or could signal a more serious problem if severe or persistent.
Constipation	Difficulty having bowel movements or having fewer bowel movements than usual.	Can affect adherence and should be described in practical terms.
Hypoglycemia	Low blood sugar. Symptoms may include shakiness, sweating, hunger, confusion, or feeling weak.	Risk can be higher when used with insulin or medicines that increase insulin release.
Hypersensitivity reaction	An allergic reaction, which may include rash, itching, swelling, or trouble breathing.	Severe symptoms require urgent medical evaluation.
Gallbladder disease	Problems with the gallbladder, which can cause pain in the upper stomach area, nausea, vomiting, or fever.	Should be separated from routine GI discomfort because it may require medical care.

Label-based context paragraph

In placebo-controlled clinical trials, gastrointestinal adverse reactions were reported more often in patients receiving semaglutide than in those receiving placebo. The FDA label lists nausea, vomiting, diarrhea, abdominal pain, and constipation among common adverse reactions reported in at least 5% of semaglutide-treated patients. The label also notes that trial adverse reaction rates may not directly reflect rates observed in practice because clinical trials are conducted under varying conditions.

Patient-facing safety paragraph

Some people taking semaglutide have stomach-related side effects such as nausea, vomiting, diarrhea, stomach pain, or constipation. These side effects may be more noticeable when the dose is being increased. Tell your health care provider if side effects are severe, do not go away, or make it hard for you to eat or drink. Get medical help right away for symptoms such as trouble breathing, swelling of the face or throat, severe stomach pain, or signs of very low blood sugar.

Reviewer-facing annotation

This patient-facing paragraph intentionally avoids giving individualized management instructions, avoids unsupported reassurance, and keeps serious symptoms distinct from common GI effects. It also avoids copying long label passages verbatim while preserving the label-based hierarchy of common adverse reactions and warnings/precautions.

Selected Public Sources Used for Mock Sample

2. U.S. Food and Drug Administration. Ozempic (semaglutide) injection prescribing information. Revised 2025.