Glossary

- Abdomen—The part of the body between the chest and the pelvis. It contains the organs of the digestive system.
- Abdominal adhesions—Abnormal bands of fiber that form in the abdomen and connect organs and tissues, causing them to stick together.
- Adhesive peritonitis—Inflammation of the lining of the abdomen caused by inflammation of abdominal organs that are sticking together.
- Body mass index (BMI)—A common measure that uses height and weight to find out if a person’s weight is in a healthy range.
  - 18.5-24.9 kg/m²: healthy
  - 25-29.9 kg/m²: overweight
  - 30 kg/m² or higher: obese
- Colon—The large intestine, part of the digestive system where undigested food is broken down and water and electrolytes are absorbed by the body.
- Crohn’s disease—A disease that causes painful inflammation in the digestive system.
- Diverticula—Pouches of tissue from the large intestine that can become inflamed and painful and may cause bleeding.
- Esophagus—The tube that allows the passage of food, liquids, and saliva from the mouth to the stomach.
- Esophageal rings or webs—Folds that can form in the esophagus and block food from passing through easily to the stomach.
- Intestinal obstruction—A condition in which food and waste products are blocked from passing through the intestines.

Introduction

Plenity is an oral capsule that helps you manage your weight. It is taken with water 2 times a day before lunch and dinner. It works in your stomach to help you feel full and eat less food throughout the day. Plenity is made with 2 natural ingredients, cellulose and citric acid.

When taken with water, Plenity capsules release gel particles in your stomach. The particles absorb water and mix with food to help you feel full sooner. That helps you to eat less.

Plenity passes through your digestive system and breaks down in the colon. The water is released from the Plenity particles and reabsorbed by your body. The particles then pass out of your body in normal bowel movements (not absorbed).
Plenty should be taken with water twice a day, 20 to 30 minutes before lunch and 20 to 30 minutes before dinner. Each dose includes 3 capsules of Plenty provided in a single pod.

For each dose, follow these steps:
1. Check that the capsules are not broken, crushed, or damaged. (Throw away any damaged capsules.)
2. Swallow the 3 capsules with water.
3. After you take the capsules, drink 2 more glasses of water (8 fl oz/250 mL each).
4. After taking Plenty, wait 20 to 30 minutes before starting your meal.

If a pre-meal dose is missed, take Plenty during or immediately after that meal.

To avoid impact on the absorption of medications:
- For all medications that should be taken with food, take them after starting a meal.
- For all medications that should be taken without food (on an empty stomach), continue taking on an empty stomach or as recommended by your physician.

**Warnings and Safety Information**

**Warnings**

- Read this package insert in its entirety before using Plenty.
- Keep out of reach of children.
- Do not use Plenty after the expiration date printed on the tube.

On an empty stomach, Plenty can affect how your body absorbs medications you take at the same time. Please take Plenty according to the Directions for Use above.

**Precautions**

- Contact a doctor right away if problems occur. If you have a severe allergic reaction, severe stomach pain, or severe diarrhea, stop using Plenty until you can speak with your doctor.
- If you have a medical condition that makes it hard to swallow, you may have trouble swallowing Plenty.
- Use Plenty with caution if you:
  - have problems with your esophagus, including webs and/or rings.
  - have diverticula
  - are likely to have strictures (a narrowing in the intestines, such as patients with Crohn’s disease may have).
  - have had gastrointestinal surgery with complications (for example, obstruction and/or adhesive peritonitis or known abdominal adhesions).
  - have active gastrointestinal conditions such as gastroesophageal reflex disease (GERD), ulcers, or heartburn.

**Possible Risks Related to Plenty**

In clinical trials, side effects with Plenty were similar in number to placebo (sugar pill). The most common side effects were diarrhea, distended abdomen, infrequent bowel movements, and flatulence.

**Potential side effects, compared to placebo**

<table>
<thead>
<tr>
<th>Greater than placebo</th>
<th>Equivalent to placebo</th>
<th>NOT observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>All GI-related adverse events combined (98% mild or moderate)</td>
<td>Distended abdomen</td>
<td>Negative health effects due to weight loss</td>
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<tr>
<td></td>
<td>Abdominal pain</td>
<td>Allergic reaction</td>
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<td></td>
<td>Bloating</td>
<td>Bowel obstruction</td>
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<td></td>
<td>Irregular bowel movements</td>
<td>Choking</td>
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<td></td>
<td>Changes to frequency and consistency of bowel movements</td>
<td>Death</td>
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<td></td>
<td>Constipation</td>
<td>Dehydration</td>
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<td></td>
<td>Cramping</td>
<td>Electrolyte problems</td>
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<td></td>
<td>Diarrhea</td>
<td>Inability to control bowel movements</td>
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<td></td>
<td>Indigestion</td>
<td>Slow or stopped movement of food through GI system</td>
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<td></td>
<td>Trouble swallowing</td>
<td>Effects on absorption of medication</td>
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<td></td>
<td>Belching</td>
<td>Need for emergency surgery</td>
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<td></td>
<td>Flatulence</td>
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<td></td>
<td>Acid reflux</td>
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<td></td>
<td>Vomiting</td>
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*Rates observed in a clinical trial.