Plenity is supplied in double blister packs that, together, provide the 2 doses taken daily. Each individual blister pack holds a single dose of 3 capsules, to be administered with water before lunch and dinner.

When combined with a healthy diet and exercise, Plenity can help you manage your weight.

Who can take Plenity?
Plenity is to aid in weight management in people who are overweight or obese and have a body mass index (BMI) of 25 to 40.

Who cannot take Plenity?
You cannot take Plenity if you:
• Are pregnant
• Have had allergic reactions to cellulose, citric acid, sodium stearyl fumarate, gelatin, or titanium oxide

Storage
Blister packs should be kept closed and stored at room temperature between 41° and 86° Fahrenheit (F) [5°–30° Celsius (C)].

Plenity should be kept in its original blister packs until use.

Directions for use
Plenity should be taken with water twice a day, 20-30 minutes before lunch and 20-30 minutes before dinner. Each dose includes 3 capsules of Plenity provided in a single blister pack.

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 Plenity, wait 20-30 minutes before starting your meal.

If a pre-meal dose is missed, take Plenity 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 Plenity. Keep out of reach of children.

On an empty stomach, Plenity can affect how your body absorbs medications you take at the same time. Please take Plenity 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 Plenity until you can speak with your doctor.
• If you have a medical condition that makes it hard to swallow, you may have trouble swallowing Plenity.
• Use Plenity with caution if you:
  o have problems with your esophagus, including webs and/or rings.
  o are likely to have strictures (a narrowing in the intestines, such as patients with Crohn’s disease may have).
  o have had gastrointestinal surgery with complications (for example, obstruction and/or adhesive peritonitis or known abdominal adhesions).

Possible risks related to Plenity
In clinical trials, side effects with Plenity were similar in number to placebo (sugar pill). The most common side effects were fullness, bloating, flatulence, and/or abdominal pain.

<table>
<thead>
<tr>
<th>Potential side effects, compared to placebo*</th>
<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>Abdominal pain</td>
<td>Negative health effects due to weight loss</td>
</tr>
<tr>
<td>Bloating</td>
<td>Irregular bowel movements</td>
<td>Changes to frequency and consistency of bowel movements</td>
<td>Allergic reaction</td>
</tr>
<tr>
<td>Constipation</td>
<td>Cramping</td>
<td>Diarrhea</td>
<td>Bowel obstruction</td>
</tr>
<tr>
<td>Indigestion</td>
<td>Trouble swallowing</td>
<td>Belching</td>
<td>Choking</td>
</tr>
<tr>
<td>Trouble swallowing</td>
<td>Flatulence</td>
<td>Acid reflux</td>
<td>Death</td>
</tr>
<tr>
<td>Trouble swallowing</td>
<td>Acidity</td>
<td>Vomiting</td>
<td>Dehydration</td>
</tr>
<tr>
<td>Problems</td>
<td>Gastrointestinal</td>
<td>&amp;</td>
<td>Electrolyte problems</td>
</tr>
<tr>
<td>Need for emergency surgery</td>
<td>problems</td>
<td>Health effects due to weight loss</td>
<td>Inability to control bowel movements</td>
</tr>
<tr>
<td>Effects on absorption of medication</td>
<td>Need for emergency surgery</td>
<td>Sloughing</td>
<td>Slow or stopped movement of food through GI system</td>
</tr>
<tr>
<td>Need for emergency surgery</td>
<td>Need for emergency surgery</td>
<td>Effects on absorption of medication</td>
<td>Need for emergency surgery</td>
</tr>
</tbody>
</table>
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.
  - 18-25: healthy
  - 25-30: overweight
  - 30 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 just 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).