

Plenity®

Patient Information Booklet

Rx only


GELESIS®

Please talk to your healthcare provider if you have any questions or do not understand any of this information.

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Introduction

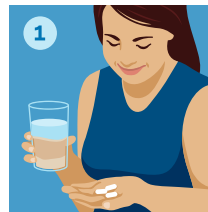
Plenity® is an oral capsule that helps you manage your weight. It is taken with water 2 times a day before lunch and dinner. It works in your stomach to help you feel full and eat less food throughout the day. Plenity® is made with 2 natural ingredients, cellulose and citric acid.

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.

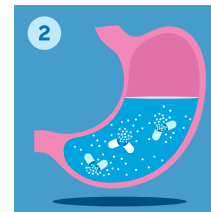
Plenity® passes through your digestive system and breaks down in the colon. The water is released from the Plenity® particles and reabsorbed by your body. The particles then pass out of your body in normal bowel movements (not absorbed).

Plenity® is supplied in pods. Each individual pod holds a single dose of 3 capsules, to be administered with water before lunch and dinner.

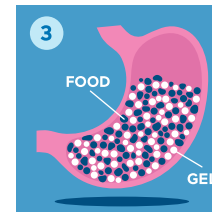
When combined with a healthy diet and exercise, Plenity® can help you manage your weight. In the GLOW clinical trial, 59% of individuals taking Plenity for 6 months lost 5% or more compared to 42% in the placebo group. Individuals on Plenity lost on average 6% vs individuals on placebo, who lost on average 4%.



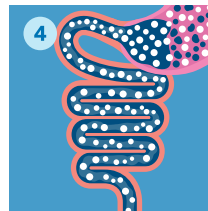
Plenity® is administered as capsules prior to a meal.



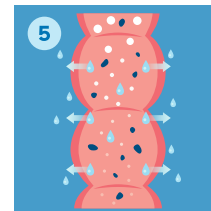
After swallowing Plenity®, you should drink water.



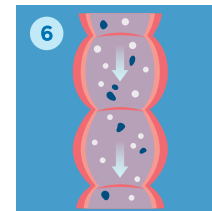
Plenity® particles hydrate in the stomach, then mix with food to create more volume.



Plenity® particles maintain their gel form and volume as they pass through the small intestine.



As Plenity® particles degrade in the colon, water is released and reabsorbed in the colon.



Degraded Plenity® particles pass through the colon and are eliminated in the bowel movement.

Who can take Plenity®?

Plenity® is indicated to aid weight management in adults with excess weight or obesity, a Body Mass Index (BMI) of 25-40 kg/m² when used in conjunction with diet and exercise.

Storage

Pods 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 pod until use.

Directions for Use

Plenity® 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 Plenity® 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 Plenity®, wait 20 to 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.

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 dioxide

Warnings and Safety Information

Warnings

- ⚠ **Read this package insert in its entirety before using Plenity®.**
- ⚠ **Keep out of reach of children.**
- ⚠ **Plenity® may alter the absorption of medications. Please review the "Directions for Use" section carefully.**
- ⚠ **Do not use Plenity® after the expiration date printed on the tray or box.**

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" section.

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:
 - 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 reflux disease (GERD), ulcers, or heartburn.
- Do not consume Plenity® if pod or package is damaged.
- Do not take any capsules which are broken, crushed, or damaged. Discard those capsules.
- Plenity® is NOT a food substitute. It is not absorbed by the body and therefore has no nutritional value.
- Plenity® should be taken under the direction of a healthcare provider as part of a structured weight loss program. Failure to adhere to prescribed dietary and exercise instructions may result in failure to lose weight.

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 diarrhea, distended abdomen, infrequent bowel movements, and flatulence.

Potential side effects, compared to placebo*		
Greater than placebo	Equivalent to placebo	NOT observed
<ul style="list-style-type: none"> All GI-related adverse events combined (98% mild or moderate) 	<ul style="list-style-type: none"> Distended abdomen Abdominal pain Bloating Irregular bowel movements Changes to frequency and consistency of bowel movements Constipation Cramping Diarrhea Indigestion Trouble swallowing Belching Flatulence Acid reflux Vomiting 	<ul style="list-style-type: none"> Negative health effects due to weight loss Allergic reaction Bowel obstruction Choking Death Dehydration Electrolyte problems Inability to control bowel movements Slow or stopped movement of food through GI system Effects on absorption of medication Need for emergency surgery

*Rates observed in a clinical trial.

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.

Explanation of Symbols

ISO 15233-1

Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied



Catalog number



Caution



Batch code



Temperature limit



Use-by date



Consult instructions for use



Manufacturer



Do not use if package is damaged



Keep dry



Prescription use only

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