

epitomee **Patient Information**
Rx only

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

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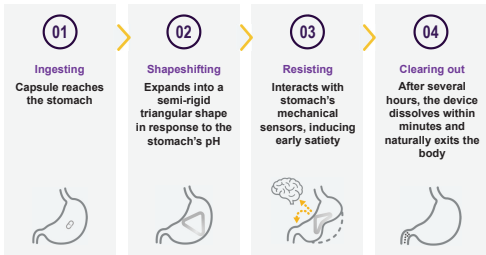
1. Introduction

Epitomee® is an oral capsule that helps you manage your weight. It is taken with water 2 times a day, 30 minutes before lunch and dinner. It works in your stomach to help you feel full and eat less food throughout the day.

When taken with water, Epitomee® releases compartments filled with gel particles that form a triangular shape in the stomach (see Figure). The particles absorb water, and the compartments swell. This helps you feel full sooner and eat less.

Epitomee® passes through your stomach and breaks down in the small intestine to small particles. Then the particles pass out of your body in normal bowel movements (not absorbed).

Epitomee® is supplied in a carton box containing either 1 blister tray or 4 blister trays. The blister tray holds 14 single doses, each dose of one capsule, to be administered with water before lunch and dinner.



Epitomee® ingestion and passage through GI tract

When combined with a healthy diet and exercise, Epitomee® can help you manage your weight. In the RESET clinical trial, 56% of the individuals taking Epitomee® for 6 months lost 5% or more of body weight. Individuals on Epitomee® lost on average 6.6% of their weight.

2. Who can take Epitomee®?

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

3. Who Cannot Take Epitomee®?

You cannot take Epitomee® if you:

- are pregnant
- have had allergic reaction to one or more of the epitomee® components: cross-linked polyacrylic acid sodium salt, hydroxy propyl methyl cellulose (HPMC), cellulose acetate phthalate, hydroxypropyl cellulose, chitosan (vegan), diethyl Phthalate, polyvinyl alcohol polyethylene copolymer (Kollicoat), triethyl citrate, cellulose acetate, acetyl tributyl citrate.

4. Storage

- Epitomee[®] capsules should be kept closed in the blister and stored at room temperature (between 59°F - 77°F / 15°C - 25°C).
- Epitomee[®] capsules should be kept in their original package until use.

5. Directions for Use

Epitomee[®] capsule should be taken with water twice a day, 30 minutes before lunch and 30 minutes before dinner. Each dose includes 1 capsule of Epitomee[®] provided in a blister tray.

For each dose, follow these steps:

1. Check that the capsule is not broken, crushed, or damaged (Throw away any damaged capsule)
2. Swallow one capsule with two glasses of water (8 fl oz/250 ml each). Taking the capsule with beverages other than water could lead to ineffective treatment.
3. After taking Epitomee[®], wait about 30 minutes before starting your meal.

It is recommended to drink water regularly throughout the day in addition to the water you drink with the capsule.

If a pre-meal dose is missed, take Epitomee[®] during that meal while following the directions for use and swallow one capsule with two glasses of water.

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 are taken once daily, take them either before taking the Epitomee[®] capsule in the morning (fasting or with breakfast) or after taking the Epitomee[®] capsule at bedtime and as prescribed by your physician.

6. Warnings and Safety Information

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

On an empty stomach, Epitee® can affect how your body absorbs medications you take at the same time. Please take Epitee® according to "**Directions for Use**" section.

6.1 Precautions

- Contact a doctor right away if problems occur. If you have a severe or continued adverse event. If you have a severe allergic reaction or severe stomach pain, stop using Epitee® until you can speak with your doctor.
- If you have a medical condition that makes it hard to swallow, you may have trouble swallowing Epitee®.
- Consult with your physician if you are taking drugs that cause ileus (such as opioids and tricyclic antidepressants).
- Use Epitee® with caution if you have active gastrointestinal conditions such as gastro-esophageal reflux disease (GERD), ulcers or heartburn.

- Avoid using Epitomee® if you:
 - have problems with your esophagus, including webs and/or rings.
 - have a diverticula.
 - are likely to have strictures (a narrowing of the intestine 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).
- Do not consume Epitomee® if blister or package are damaged.
- Do not take any capsule which is broken, crushed, or damaged. Discard this capsule.
- Epitomee® is NOT a food substitute. It is not absorbed by the body and therefore has no nutritional value.
- Epitomee® should be taken under the direction of a health care 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.

6.2 Possible Risks Related to Epitomee®

In the clinical study, side effects with Epitomee® were similar in number to placebo (dummy capsule). The most common side effects were infections (the study was performed during the **COVID-19** pandemic) abdominal discomfort (pain cramping), constipation, headache and nausea.

Potential GI Adverse Events (rates observed compared to placebo)*

Greater than Placebo	Lower than Placebo	Equal to Placebo	Not observed
• Abdominal discomfort (pain, cramping)	• Constipation • Nausea • Abdominal distension (bloating) • Flatulence • GERD • Vomiting	• All GI adverse events combined (93.5% mild) • Diarrhea	• Negative health effects due to weight loss • Allergic Reaction • Bowel obstruction • Choking • Death • Slowed or stopped movement of food through the GI system • Effects on absorption of medication • Need for emergency surgery

*Rates observed in the RESET pivotal study

7. 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.
- **Ileus** – Lack of normal movement somewhere in the intestines that leads to a buildup and potential blockage of food material.
- **Intestinal obstruction** – A condition in which food and waste products are blocked from passing through the intestines.

8. 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

 Do not use if package is damaged

 Prescription use only

Epitomee® Medical Ltd. 17 Hatochen St. Caesarea 3079892, Israel.	Manufactured by: Epitomee® Medical Ltd. 17 Hatochen St. Caesarea 3079892, Israel.
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Patent: www.epitomeemedical.com/patents

epitomee

shaping your health