

Warnings:

- The Vibrant Capsule is MR (magnetic resonance) unsafe. The device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. Undergoing an MRI (magnetic resonance imaging) while the Capsule is inside your body may result in patient injury, including serious damage to your intestinal tract or abdominal cavity.
 - If you require an MRI, instruct your physician to verify Capsule expulsion via abdominal X-ray before undergoing an MRI examination.
- After ingesting a Vibrant Capsule and until it is excreted, you should not be near any source of powerful electromagnetic fields such as one created near an MRI device.
- The Capsule should be kept away from implants such as pacemakers, defibrillators, nerve stimulators, and other devices that could be affected by proximity to a DC (direct current) magnetic field.
- If you have reasonable doubt concerning the integrity of a Vibrant Capsule, it should not be used and should be discarded.
- Under no circumstances should a Vibrant Capsule be swallowed without prior activation in the Pod.
- If after ingesting a Vibrant Capsule you will experience one of the following symptoms, contact a physician immediately and stop taking additional Capsules until instructed by your physician
 - Black, bloody or tarry stools;
 - Abnormal abdominal pain, including new onset of abdominal pain, change in the character of a previously existing abdominal pain, or persistent abdominal pain;
 - Nausea or vomiting; or
 - Believe a Capsule has not been expelled from the body, such as if no Capsule has been expelled from the body after 2 weeks from the time of ingestion;
- Vibrant Capsules must be stored in a safe place, out of the reach of children and/or infants.
 - If a child has accidentally swallowed an unused Vibrant Capsule, he/she should be brought immediately to a hospital.
- Use of Vibrant equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF (radio frequency) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Vibrant Pod, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Users should inspect the Pod and Capsule blister pack for possible tampering. If you suspect someone tampered with the Pod, then the device should not be used. If you suspect someone tampered with the blister cell for a Capsule, then that Capsule should not be used. Signs of possible tampering include, but are not limited to:
 - For the Pod - cracks or breaks in the Pod casing, scratches around the screw holes, and scratches/marks around the USB port that the user does not recognize.
 - For the Capsule - damage to the blister cell, or the Capsule is not in a sealed blister cell.
- Patients with pelvic floor dyssynergia may have impaired muscular ability to evacuate stool; therefore, they should be monitored for any signs of adverse response and to ensure ability to pass the Capsule.
- The use of this product has not been studied in patients who chronically use non-steroidal anti-inflammatory drugs (NSAIDs). Chronic use is defined as taking full dose NSAIDs more than three times a week for at least six months.

Precautions

- Do not use Pod or Capsules if packaging is damaged.
- Read this package insert in its entirety before using the Vibrant Capsule.
- Do not use the Pod if there are any changes or modifications made to it that are not expressly approved by Vibrant Ltd.
- A Vibrant Capsule should not be ingested after its expiration date.
- Avoid biting the Vibrant Capsule prior to swallowing.
- Long-Term Use: The safety and effectiveness of the Vibrant System for long-term use in the indicated population, i.e., for more than 8 weeks, has not been evaluated. Therefore, a physician who elects to use the Vibrant System for extended periods in adults with chronic idiopathic constipation, who have not experienced relief of their bowel symptoms by using laxative therapies, should re-evaluate the individual patient including for long-term