

⚠ 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, the components of the Vibrant System and the other non-Vibrant equipment should be checked 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 (condition where the muscles in the pelvic floor no longer work in unison) 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 Vibrant System has not been assessed in patients with chronic use of non-steroidal anti-inflammatory drugs (NSAIDs). Chronic use means taking full dose NSAIDs more than three times a week for at least six months.

Precautions

- Do not use the Pod or Capsules if packaging is damaged.
- Read this patient label and the instructions for use in its entirety before using the Vibrant System.
- A Vibrant Capsule should not be taken 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 has not been evaluated. Long-term use means more than 8 weeks. Therefore, a physician who decides to prescribe the Vibrant System to a patient for longer than 8 weeks should re-evaluate the individual patient including for long-term usefulness of the device.

What are the Expected Benefits and Risks of Using the Vibrant System?

The Vibrant System is expected to improve symptoms of chronic idiopathic constipation (see description above). The primary expected benefit is an increase in bowel movements that are associated with a feeling of complete evacuation, without the need for medication. The pivotal clinical study of the Vibrant System showed that nearly twice as many patients had at least 1 more of this type of bowel movement per week while using the Vibrant System compared to patients who used a placebo (inactive biodegradable softgel Capsule) treatment (40% versus 22%). The study also found that more patients reported improvement in quality of life after using the Vibrant System compared to patients who used the placebo treatment (77.9% versus 66.2%). Patients who used the Vibrant System reported less straining during bowel movements and improved stool consistency (less lumpy or hard) than patients who used the placebo treatment.

Based on clinical testing, potential side effects associated with the use of this device may include abdominal pain, abdominal distension (swollen abdomen), abdominal discomfort, vomiting, nausea, blood in stool, diarrhea, flatulence (passing gas) and proctalgia (pain due to a spasm of the pelvic floor muscles). In rare cases, obstruction may occur.

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