

## Safety of the Ullorex® Oral Intra-gastric Balloon for the Treatment of Obesity

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### Abstract

#### **Background:**

Intra-gastric balloons have been used for weight loss with varying success. Widespread use of intra-gastric balloons has been limited because balloons must be placed in, and removed from, the stomach endoscopically. Development of a balloon that does not require endoscopy suggests that obesity treatment with intra-gastric balloons is feasible. The purpose of this study was to test the Ullorex® oral intra-gastric balloon (OIB) in a sample of human participants.

#### **Methods:**

The Ullorex OIB is a large capsule that is injected with citric acid and swallowed. After 4 minutes, the balloon inflates to 300 cm<sup>3</sup>. Stomach acid degrades a plug on the balloon over 25–30 days, when the balloon deflates and passes in feces. The Ullorex OIB was tested in 12 humans (two participants received placebo capsules). Body weight was monitored before and after balloon placement, and test meals quantified food intake among 6 of the 12 participants, all of whom received one balloon.

#### **Results:**

A single significant adverse event occurred. The one participant randomized to receive three balloons developed nausea and vomiting, requiring intravenous fluids, which was likely influenced by noncompliance (eating solid foods after balloon placement). Participants who received balloons had a significant mean weight loss over 2 weeks, amounting to 1.5 kg ( $p < 0.05$ ). A marginally significant food intake reduction from baseline to week 1 was found (149 kcal, 24.4%) ( $p = 0.055$ ).

#### **Conclusions:**

The Ullorex OIB was successfully utilized in this study, with one serious adverse event that was likely influenced by noncompliance. Body weight and food intake data suggest that the Ullorex OIB be tested further as a possible treatment for obesity.

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**Abbreviations:** (AEs) adverse events, (BIB) BioEnterics intra-gastric balloon, (BMI) body mass index, (CBC) complete blood count, (EI) energy intake, (GIB) Garren gastric balloon, (ISO) International Standards Organization, (KUB) abdominal X-ray, (OIB) oral intra-gastric balloon, (RD) registered dietitian, (VAS) visual analogue scales

**Keywords:** balloon, device, food intake, gastric, obesity

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