

# RefluG™

## ISOREPAIR



(MEDICAL DEVICE)

## A NEW BARRIER THERAPY FOR GASTROESOPHAGEAL REFLUX

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out-licensing  
under private  
label

“ RefluG™ Isorepair is an innovative medical device designed to reduce gastroesophageal reflux symptoms through a topical protectant and regenerative effect of the esophageal mucosa. ”



### GASTROESOPHAGEAL REFLUX DISEASE (GERD): OVERVIEW

Gastroesophageal reflux disease (GERD) occurs when stomach acid frequently flows back into the esophagus. GERD is caused by multiple different mechanisms that may lead to the disruption of the esophagogastric junction barrier resulting in exposure of the esophagus to acidic gastric contents.

Most of the patients with GERD fall into two main phenotypes which have different

pathophysiological and clinical characteristics: nonerosive reflux disease (NERD) or erosive esophagitis. In particular, NERD is characterized by common reflux symptoms, mainly heartburn, in the absence of visible esophageal mucosal injury at endoscopy.

Unlike patients with erosive esophagitis, NERD patients have a significantly lower response rate to proton pump inhibitor (PPI) therapy.

## TARGET AND INDICATIONS:

- **RefluG™ Isorepair** is a liquid gel indicated for the treatment of common GERD symptoms including heartburn, regurgitation, retrosternal pain, difficulty of swallowing, chronic cough and acid taste.
- Effective on its own in subjects with mild symptoms or in combination with a Proton Pump Inhibitor (PPI) particularly in those who are non-responsive or partial responsive to PPI treatment.

## HIGHLIGHTS:

- Gluten and lactose free
- Natural cherry flavor
- Vegan and vegetarian friendly

## FUNCTIONAL SUBSTANCES:

- **Mucoadhesive polymers:** form a physical layer coating the esophageal epithelium thus avoiding the stimulation of the nociceptive receptor causing pain.
- **Hyaluronic acid:** due to its water-binding capacity creates a protective film at the mucosal level preventing damage.
- **Amino acids:** reinforce the integrity of the mucosal lining.
- **Rice starch (VGF®):** the soothing properties of VGF® helps to reduce mucosal irritation.

## HOW DOES IT WORK

**RefluG™ Isorepair** has been developed to protect the esophageal mucosa and to support its physiological reparative mechanism.

**RefluG™ Isorepair** relieves GERD symptoms through local physical actions:

- 1 Coats the esophagus creating a long-lasting barrier against both acidic and non-acidic reflux
- 2 Strengthens the esophageal barrier and promotes the repair of damaged tissue
- 3 Provides a lubricant and anti-irritative action favoured by the filming effect

## PACKAGES AVAILABLE

**RefluG™ Isorepair** is available in single-dose liquid sachets (10ml) – pack of 12 or 20.

## SCIENTIFIC EVIDENCE AND PROPRIETARY STUDIES:

Protective and regenerative effects of a novel medical device against esophageal mucosal damage using *in vitro* and *ex vivo* models (Agostinis et al 2020)

A randomized, double-blind, placebo-controlled pilot study to evaluate the efficacy and tolerability of a novel oral bioadhesive formulation for the treatment of nonerosive reflux disease-related symptoms (Ribaldone et al 2020)



\*Registered as "RefluG Isorepair (NB 0476)".