

RefluZero

MEDICAL DEVICE FOR THE TREATMENT OF
HEARTBURN AND GASTROESOPHAGEAL REFLUX



ANTI-REFLUX MELT IN MOUTH TABLET

Gastroesophageal reflux disease (GERD) is a functional disease associated with a number of typical symptoms, such as:

- Heartburn (retrosternal pyrosis)
- Acid or alkaline regurgitation from lying down, or from food or irritating substances that can cause reflux (alcohol, coffee, tea, chocolate, citrus fruit, etc.)
- Cramps
- Non-painful difficulty in swallowing (dysphagia)
- An irritating cough
- Dysphonia (hoarseness, aphonia)

These symptoms may or may not be associated with erosive inflammatory lesions of the esophageal mucosa. Poor diet or a stressful lifestyle can have a major effect on the production of gastric juices, increasing gastric acid and causing an irritating and painful burning sensation, especially after meals. This excessive acidity may also be felt at the stomach entrance, with sensations of burning, cramp, bloatedness and nausea. GERD can also occur during sleep as lying down causes gastric juices to flow into the oesophagus. Because the walls of the esophagus are not designed to tolerate gastric acid, this causes a burning sensation in the chest.

INDICATIONS

RefluZero is a medical device with a mechanical action that is indicated for:

- Symptomatic treatment of gastroesophageal reflux disease. Rapidly reduces associated symptoms, such as: heartburn (pyrosis), acid regurgitation, epigastric pain, irritating cough and dysphonia.
- In the symptomatic treatment of hyperacidity (occasional pain and burning in the stomach).

RefluZero is an original and innovative combination of **chondroitin sulfate, hyaluronic acid and aluminium hydroxide**. **RefluZero** protects against the irritating action of hydrochloric acid produced by the stomach.



- *Tablets are initially melt in mouth, stimulating salivation and giving better contact between the ingredients and the esophageal wall, which increases protection and lubrication.*
- *Chondroitin sulfate adheres to the gastroesophageal mucosa, protecting it by insulating against attack from gastric juices.*
- *Hyaluronic acid, combined with the adhesive properties of chondroitin sulfate, helps protect and repair damaged tissue of the oesophagus.*
- *Aluminium hydroxide acts as an antacid, reducing the impact of gastric juices on the damaged mucosa.*

COMPOSITION Chondroitin sulfate sodium salt, sucrose, aluminium hydroxide, calcium carbonate, anticaking agents: mono-, di-, and triglycerides of fatty acids, silicon dioxide, high molecular weight sodium hyaluronate; fragrance; sweetener: ammonium glycyrrhizinate.

PACKAGING 20 melt in mouth tablets of 1100 mg.

DOSES AND DIRECTIONS FOR USE

DOSES: **Adults and children over 12 years:** 1-2 tablets after main meals and/or before going to bed, or as needed in the event of symptoms such as stomach pain and burning, in accordance with medical advice. **Children over 6 years:** it is advised to use the product only after consulting your doctor. 1 tablet after main meals and/or before going to bed, or as needed in the event of symptoms such as stomach pain and burning. If necessary, the tablet can be divided into two equal doses.

DIRECTIONS FOR USE: Start by dissolving the tablets in the mouth and then chew them. Water or milk may be taken after ingestion.

UNDESIRABLE EFFECTS Prolonged use of the product may cause constipation due to the astringent action of the aluminium.

CONTRAINDICATIONS Kidney failure. Hypophosphatemia. Known hypersensitivity to one of the ingredients.

PREGNANCY AND BREAST FEEDING Use the product after consulting your doctor.

WARNING

The product does not contain gluten, lactose and milk derivatives.

The product contains aluminum, which could interfere with the absorption of drugs. Citrates can increase the absorption of aluminum. If you are taking any drug consult your doctor before use the product, do not take drugs 1 hour before and 2 hours after taking the product.

Do not exceed the recommended dose. In the event of an adverse reaction, stop the treatment and consult a doctor. Following a short period of treatment without noticeable results, consult a doctor.

The product contains sucrose, which should be taken into account by diabetic patients.

Do not use the product after the expiry date indicated on the packaging. The expiry date applies to the product when properly stored in intact packaging.

Store in a cool and dry place, away from sources of heat.

Keep out of reach of children.



Rev. 04 04/2018 it / eng

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to be
completed with
the local legal
entity

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