

BIEFFE HCP**SAFETY AND PERFORMANCE INFORMATION - "Multidose bottle 200 ml"****BIEFFE HCP**

Medical device for the treatment of gastroesophageal reflux
Oral solution 200 ml bottle

INDICATIONS

BIEFFE HCP is a medical device indicated to reduce symptoms related to gastro-oesophageal reflux such as: pyrosis, epigastric pain, acid regurgitation, irritating cough, dysphonia. **BIEFFE HCP** can be taken during therapy with proton pump inhibitors (PPIs).

HOW TO TAKE

Adults and children over 12 years old: shake the bottle before use. Take 10 ml of oral solution after mains meal and at bedtime, up to 4 times a day. To correctly dose the product, use the measuring cup contained in the pack, filling it up to 10 ml notch. After each use, clean the measuring cup thoroughly with water and place it in the box.
Administration in children should be under adult supervision.

COMPOSITION

Sodium hyaluronate (1,02%), sodium chondroitin sulphate (only for L-1R0S variant: fish) (2,53%), poloxamer 407 (2,70%), polyvinylpyrrolidone (2,50%), xylitol, sodium benzoate, potassium sorbate, red grapes flavor, hydrochloric acid, water.

CONTRAINDICATIONS

In children younger than 12 years and in pregnant and breastfeeding women, due to lack of extensive data on these populations, it is advisable not to use the product.

Do not use the product in case of hypersensitivity to one or more components.

In case of undesired reactions discontinue treatment and consult your doctor.

WARNINGS

Consult your doctor before using the product, in case you need to take other oral treatments, especially anticoagulants.

Do not use after expiry date stated on the package.

Do not use if the packaging has been opened or damaged.

If symptoms persist after 14 days of treatment, it is recommended to consult your doctor.

Do not exceed the recommended dose.

Report to the manufacturer and to the competent authority any serious incident that occurs in connection with the use of the device

HOW TO STORE

Keep out of the reach and sight of children.


Store in a cool and dry place (0-30°C), protected from light and away from heat sources. Do not freeze.

Once opened, use the product within 2 months

The expiry date refers to the product properly stored, in its integral package.

Summary of safety and clinical performance is available on medical device database (Eudamed public website: <https://ec.europa.eu/tools/eudamed>) with Basic UDI-DI: 8053307840002XF

PACK

200 ml bottle with measuring cup. Measuring cup is a medical device  0373 manufactured by Bormioli Pharma SpA, Corso Magenta, 84 – 20123 Milano - Italy

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