BIEFFE HCP
SAFETY AND PERFORMANCE INFORMATION - *"Single-dose sachet 10 ml"*

BIEFFE HCP
Medical device for the treatment of gastroesophageal reflux
Oral solution 10 ml single-dose sachet
n. single-dose sachets

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: Take one single-dose sachet, after mains meal and at bedtime, up to 4 times a day. BIEFFE HCP can be drunk directly from the sachet.
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

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