

OMEPRAZOLE

10mg/15ml, 20mg/15ml oral solution

PROFILE

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| Classification | Medicinal product, Rx |
| ATC code (3rd level) | A02B Drugs for peptic ulcer and gastro-oesophageal reflux disease |
| Dosage form | Oral solution |
| Active ingredients | 15 ml solution contains 10 mg or 20 mg omeprazole |
| Therapeutic indication | <p>Adults</p> <ul style="list-style-type: none"> • Treatment of duodenal ulcers • Prevention of relapse of duodenal ulcers • Treatment of gastric ulcers • Prevention of relapse of gastric ulcers • In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease • Treatment of NSAID-associated gastric and duodenal ulcers • Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk • Treatment of reflux esophagitis • Long-term management of patients with healed reflux esophagitis • Treatment of symptomatic gastro-esophageal reflux disease <p>Children over 1 month of age</p> <ul style="list-style-type: none"> • Treatment of reflux esophagitis • Symptomatic treatment of heartburn and acid regurgitation in gastro-esophageal reflux disease <p>Children over 4 years of age and adolescents</p> <ul style="list-style-type: none"> • In combination with antibiotics in treatment of duodenal ulcer caused by H. pylori <p><i>*subject to approval by the National Competent Authorities</i></p> |

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| Reference medicinal product | Losec 20 mg gastro-resistant capsules MAH: CHEPLAPHARM Arzneimittel GmbH (previously AstraZeneca B.V) |
| Target population | children over 1 month of age, adults with dysphagia and patients feed via NG or PEG tubes |

TRADE DRESS

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| Appearance | Off white to pale yellow viscous solution with menthol flavour (10 mg) and menthol and lemon flavour (20 mg). |
| Packaging description | Dual-chamber bottle consisted of HDPE cap with tamper evident ring, PP plunger and PE membrane filled with omeprazol solution and HDPE Bottle with neck filled with diluent for omeprazole solution. Dosing pipette. |
| Pack size | 14 single-dose, dual-chamber HDPE bottles |



DEVELOPMENT / PRODUCTION STATUS

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| Batch size (MOQ) | cca. 4000 packs (1 pack contains 14 single dose bottles) cca. 8000 packs (1 pack contains 14 single dose bottles)* <i>*possible scale-up</i> |
| Shelf life | 24 months kept in refrigerator at 2-8°C. Product can be used on ambient storage conditions when removed from refrigerator in a period of 28 days. |
| Additional available stability data | Climatic zone IVb -24 months kept in refrigerator at 2-8°C. Product can be used on ambient storage conditions at 30°C/75%RH when removed from refrigerator in a period of 28 days |

AVAILABLE DOSSIER

CTD/eCTD

AVAILABLE MARKETING AUTHORIZATIONS

HU, PT- concentrate and solvent for oral solution
CZ*, DK, EE, EL, FI, LT*, LV, NO*, PL*, SE, SK*, IT*- oral solution

**pending MA*

BUSINESS MODEL

License of the brand Lappoxo,
exclusive supply and distribution

COMPETITIVE EDGE / CLAIM

- First ready to drink omeprazole in liquid form (value added medicine)
- Patented formulation and packaging
- Single-dose pack
- Easy, convenient and safe to use
- Good palatability
- Free from: sugar, sorbitol, potassium, titanium dioxide, artificial coloring and parabens
- 28 days out of fridge stability
- Suitable for administration via PEG and NG tubes
- Precise dosing in infants with pipette (1 mg/kg)

