NAFAS PHARMED

RX Code: 70369

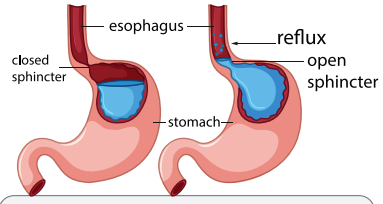

# Meglozek®

10 mg

Esomeprazole | Delayed release granule for oral Sachet

## What Meglozek® is and what it is used for

Esomeprazole belongs to a class of compound called proton pump inhibitors (PPIs) block the gastric H, K-ATPase, inhibiting gastric acid secretion. It is the S-isomer of omeprazole, which allows it to be absorbed more effectively, making it more potent in acid suppression compared to other PPIs. Meglozek® is primarily indicated for treating gastroesophageal reflux disease (GERD) by helping heal erosive esophagitis (EE) and managing heartburn and other symptoms associated GERD in both adults and pediatric patients. Additionally, it is used to prevent and reduce the risk of nonsteroidal anti-inflammatory drugs (NSAIDs)-associated gastric ulcers, and it is part of combination therapy to eradicate Helicobacter pylori, which can lead to duodenal ulcers. Meglozek® can also treat pathological hypersecretory conditions, including Zollinger-Ellison syndrome, which causes excessive stomach acid production.




**Gastroesophageal reflux disease (GERD)** is a digestive disorder in which stomach acid flows back into the esophagus, causing symptoms such as heartburn and regurgitation.

## Meglozek® pharmacodynamics

### Mechanism of Action

Esomeprazole is a proton pump inhibitor (PPI) that reduces gastric acid by targeting the H+/K+-ATPase enzyme in stomach parietal cells. Both S- and R-isomers of omeprazole convert into an active form in the acidic environment of the parietal cell, inhibiting the proton pump and thereby blocking the final step in acid production. This effect is dose-dependent and occurs at daily doses of 5 to 40 mg.

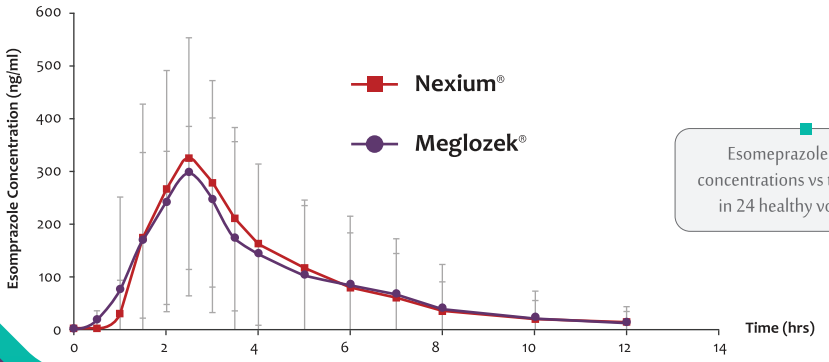
## Meglozek® pharmacokinetics

Esomeprazole is acid labile and is administered orally as enteric-coated granules. Absorption of esomeprazole is rapid, with peak plasma levels occurring approximately 1-2 hours after dose. The apparent volume of distribution at steady state in healthy subjects is approximately 0.22 l/kg body weight. Esomeprazole is 97 % plasma protein bound. The plasma elimination half-life is about 1.3 hours after repeated once-daily dosing.

## In vivo studies

The comparison of rate and extent of absorption for Esomeprazole from Meglozek® and Nexium® (brand formulation) in an in vivo environment is as follows:

The mean plasma concentrations vs time curve after single administration of the Meglozek® product and the reference Nexium® formulation, are provided in the Figure. It could be concluded that the Meglozek® and the Nexium® formulation are bioequivalent.




Esomeprazole plasma concentrations vs time profile, in 24 healthy volunteers

## Meglozek® administration and dosage

Pour the contents of the sachet into a small cup containing 5 mL of water, and stir until the granules are completely dispersed. After 3 minutes, a thick mixture will form, which should be consumed within 30 minutes. The granules should not be chewed. Meglozek® should be taken at least one hour before meals.

| Meglozek® delayed-release granules | | | |
|---|---|---|---|
| Approved uses | | Dose | Frequency & duration |
| **1 to 11 year olds** | | | |
| Short-term Treatment of Symptomatic GERD | | 10 mg | Once Daily for up to 8 weeks |
| Healing of EE: | weight < 20 kg | 10 mg | Once Daily for 8 weeks |
| | weight ≥ 20 kg | 10 mg or 20 mg | Once Daily for 8 weeks |
| **Pediatric GERD: 1 month to < 1 year old - EE due to acid-mediated GERD only** | | | |
| weight 3 kg to 5 kg | | 2.5 mg | Once Daily for up to 6 weeks |
| weight > 5 kg to 7.5 kg | | 5 mg | Once Daily for up to 6 weeks |
| weight > 7.5 kg to 12 kg | | 10 mg | Once Daily for up to 6 weeks |
| **Pediatric GERD: 12 to 17 year olds** | | | |
| Healing of EE | | 20 mg or 40 mg | Once Daily for 4 to 8 weeks |
| Symptomatic GERD | | 20 mg | Once Daily for 4 weeks |

For the treatment of Helicobacter pylori, the dosage is based on the treatment regimen, and Meglozek® is combined with antibiotics.

## Meglozek® warning and precautions

- If a patient is allergic to esomeprazole, other PPIs (like lansoprazole or omeprazole), or has known allergies, they should avoid this medication.
- Patients with liver disease or lupus should consult a healthcare provider before starting treatment.
- Certain symptoms, such as heartburn with lightheadedness, sweating, chest/jaw/arm pain, or unexplained weight loss, may indicate a more serious condition and require medical evaluation.
- Long-term or high-dose use of PPIs can increase the risk of certain nutrient deficiencies, including vitamin B12, calcium, and vitamin D. This is due to the way PPIs work by reducing stomach acid production, which plays a key role in nutrient absorption.
- Children may be more prone to side effects, such as fever or respiratory infections; consult a pediatrician for guidance.

## Meglozek® use in specific populations

- **Pregnancy:** Pregnancy category B
- **Breast-feeding:** Do not take Meglozek® if you are breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

## Meglozek® drug interaction

- May interact with drugs affected by gastric pH (e.g., ketoconazole, iron salts, digoxin). Patients on Meglozek® and digoxin should be monitored for digoxin toxicity.
- Combination of CYP2C19 and 3A4 inhibitors may increase esomeprazole levels.
- **Clopidogrel:** Meglozek® reduces exposure to its active metabolite of clopidogrel.
- **Tacrolimus:** May increase serum levels of tacrolimus.
- **Methotrexate:** May increase serum levels of methotrexate.

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Nafas Zist Pharmed Co. | Unit 101, Biotech Center Bldg
National Institute of Genetic Engineering, Pajoohesh Blvd
**Tehran, Iran | 021 9200 15 20**