Flexium

Esomeprazole Magnesium Tablets
20 mg / 40 mg

Composition:
Each uncoated tablet contains:
Esomeprazole Magnesium Trihydrate BP
eq. to Esomeprazole 20 mg
(as enteric-coated granules)

Indications:
Flexium tablets are indicated for: Gastroesophageal Reflux Disease (GERD)
Prolonged treatment following IV-induced prevention of re-bleeding of peptic ulcers.
Treatment of Zollinger-Ellison Syndrome
Gastroesophageal Reflux Disease (GERD): – Treatment of erosive reflux esophagitis: 40 mg once daily for 4 weeks.
Treatment of Zollinger-Ellison Syndrome
The recommended initial dose is Flexium 40 mg twice daily. The dose should then be adjusted individually, and treatment continued for as long as clinically indicated.
Adolescents aged 12 years and older
Gastroesophageal Reflux Disease (GERD): treatment of erosive reflux esophagitis: 40 mg once daily for 4 weeks.
Children under 12 years of age
The tablets should be swallowed whole with liquid. The tablets must not be chewed or crushed.
For patients who have difficulty swallowing, the tablets may also be dispersed in half a glass of non-carbonated water.

Contraindications:
Hypersensitivity to the active substance, to substituted benzimidazoles, or to any of the excipients used. Esomeprazole must not be used concomitantly with nelfinavir.

Warnings and special precautions for use:
In the presence of any alarm symptoms, and when gastric ulcer is suspected or present, malignancy must be excluded, as treatment with Flexium may alleviate symptoms and delay diagnosis.
Long-term use: Patients on long-term treatment (particularly those treated for more than one year) should be kept under regular surveillance. Gastrointestinal Infections
Treatment with proton pump inhibitors may lead to a slightly increased risk of gastrointestinal infections, such as Salmonella and Campylobacter.
Hypomagnesemia: Severe hypomagnesemia has been reported in patients treated with proton pump inhibitors (PPIs), such as esomeprazole, for at least three months and, in most cases, for one year.

Concomitant administration of esomeprazole with atazanavir is not recommended. An interaction between clopidogrel and esomeprazole has been observed.

Interactions with other medicinal products and other forms of interaction:
Protease inhibitors: It has been reported that omeprazole interacts with some protease inhibitors. Increased gastric pH during treatment with omeprazole may alter the absorption of protease inhibitors. For atazanavir and nelfinavir, decreased serum levels have been reported when administered concomitantly with omeprazole, and concomitant administration is not recommended. For saquinavir (with concomitant ritonavir), increased serum levels (80–100%) have been reported during concomitant treatment with omeprazole (40 mg/day).
Methotrexate: When administered concomitantly with PPIs, methotrexate levels have been shown to increase in some patients.
Diazepam: Concomitant administration of 30 mg of esomeprazole resulted in a 45% reduction in the clearance of the CYP2C19 substrate diazepam.
Phenytoin: Concomitant administration of 40 mg of esomeprazole to patients treated with warfarin in a clinical trial showed that coagulation times remained within the accepted range.

Pregnancy and Lactation:
Pregnancy: Clinical data on exposed pregnancies with Flexium are insufficient. With the racemic mixture, data on omeprazole from a larger number of exposed pregnancies, derived from epidemiological studies, indicate an absence of malformative or fetotoxic effects.
Breastfeeding: It is not known whether esomeprazole is excreted in human breast milk. There is insufficient information regarding the effects of esomeprazole on newborns/infants. Esomeprazole should not be used during breastfeeding.

Adverse Effects:
Headache, abdominal pain, diarrhea, and nausea are among the adverse reactions most commonly reported in clinical studies (as well as in post-marketing use). Furthermore, the safety profile is similar across different formulations, treatment indications, age groups, and patient populations. No dose-related adverse reactions have been identified.

Overdose:
To date, there is very limited experience with deliberate overdose. Symptoms described in connection with a 280 mg dose included gastrointestinal symptoms and weakness. No specific antidote is known. Esomeprazole is extensively bound to plasma proteins and, therefore, is not readily dialyzable.

Storage: Store in a cool, dark, and dry place, below 30ºC.
Keep medicines out of the reach of children.

Presentation: Blister pack of 7 tablets.

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