



Summary of investigation results

Esomeprazole Magnesium Hydrate

February 16, 2016

Non-proprietary name

Esomeprazole Magnesium Hydrate

Brand name (Marketing authorization holder)

Nexium Capsules 10 mg, 20 mg (AstraZeneca K.K.)

Indications

Nexium Capsules 10 mg

- Gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, non-erosive reflux disease, Zollinger-Ellison syndrome, suppress relapse of gastric ulcer or duodenal ulcer when prescribing non-steroid anti-inflammatory drugs (NSAIDs), and suppress relapse of gastric ulcer or duodenal ulcer when prescribing low-dose aspirin.
- Aid in bacterial eradication of *Helicobacter pylori* in the following diseases:
Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, stomach that has undergone endoscopic treatment for early gastric cancer, *Helicobacter pylori* gastritis

Nexium Capsules 20 mg

- Gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, Zollinger-Ellison syndrome, suppress relapse of gastric ulcer or duodenal ulcer when prescribing NSAIDs, and suppress relapse of gastric ulcer or duodenal ulcer when prescribing low-dose aspirin.
- Aid in bacterial eradication of *Helicobacter pylori* in the following diseases:
Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic



purpura, stomach that has undergone endoscopic treatment for early gastric cancer,
Helicobacter pylori gastritis

Summary of revision

“Rhabdomyolysis” should be newly added to the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of rhabdomyolysis have been reported in patients treated with esomeprazole magnesium hydrate in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 9 cases associated with rhabdomyolysis have been reported (including 6 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.