

## CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

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### PANTOPRAZOLE MAGNESIUM (Pantoloc M™ – Altana Pharma Inc.)

**Description:**

Pantoprazole magnesium is a new salt form of pantoprazole, a widely used proton pump inhibitor (PPI). It is approved for use in conditions where a reduction of gastric acid is required, such as the following: duodenal ulcer, gastric ulcer, reflux esophagitis and symptomatic gastro-esophageal reflux disease (such as, acid regurgitation and heartburn). Additionally, pantoprazole, in combination with clarithromycin and either amoxicillin or metronidazole, is approved for use in the treatment of patients with an active duodenal ulcer who are *H. pylori* positive.

**Dosage Forms:**

40 mg enteric coated tablet

**Recommendation:**

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that pantoprazole magnesium be listed in a similar manner as drug plans list other PPIs.

**Reasons for the Recommendation:**

1. The Committee considered three randomized controlled trials (RCTs) which compared pantoprazole magnesium with pantoprazole sodium in patients with reflux esophagitis. The overall results of these trials demonstrated that pantoprazole magnesium was equivalent to pantoprazole sodium in reducing gastric acid, endoscopic healing and symptom relief.
2. There is no evidence of any difference in the incidence or nature of adverse effects with pantoprazole magnesium compared with pantoprazole sodium.
3. At the price submitted by the manufacturer, the daily cost of pantoprazole magnesium (taken as 40 mg per day) is significantly less than the current price of pantoprazole sodium and similar to the current price of the least costly PPIs on the market. At these costs, switching patients from pantoprazole sodium and other more costly PPIs to pantoprazole magnesium will result in cost savings for drug plans. The manufacturer has requested that the submitted price of pantoprazole magnesium remain confidential pursuant to the Confidentiality Guidelines of the Procedure for the Common Drug Review.

**Of Note:**

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.
2. Cost savings to drug plans will occur if pantoprazole magnesium is added to formulary in place of pantoprazole sodium.
3. The cost savings associated with pantoprazole magnesium will change if the costs of other PPIs change significantly. The Committee recommends that the listing status of pantoprazole magnesium be reviewed by individual drug plans at that time.