



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Pylera™

Common Name: Bismuth subcitrate potassium/metronidazole/tetracycline

PDL Category: GI – ULCER ANTI-INFECTIVE

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Helidac® (bismuth subsalicylate/metronidazole/tetracycline)	Preferred
Prevpac® (lansoprazole/amoxicillin/clarithromycin)	Preferred with conditions

Summary

Indications and Usage: *Helicobacter pylori* (*H. pylori*) infection used in combination with omeprazole; duodenal ulcer disease caused by *H. pylori* infection.

Mechanism of Action: Bismuth Subcitrate: exact mechanism of action unknown; Metronidazole: inhibits nucleic acid synthesis; Tetracycline: Inhibits bacterial protein synthesis.

Dosage Forms: Capsules; 140/125/125mg

Recommended Dosage: Three capsules QID x 10 days

Common Adverse Drug Reactions: Dyspepsia, abdominal pain, diarrhea, nausea, headache.

Contraindications: Pregnancy, nursing mothers, renal or hepatic impairment, hypersensitivity to any component of the compound or salicylates.

Manufacturer: Axcan Pharma Inc.

Analysis: Pylera™ is an antimicrobial combination product that is used in the treatment of *H. pylori* infection. It is cautioned that to prevent the development of resistant bacteria, Pylera™ only be used when there is strong evidence that a bacterial infection is present. For complete eradication of *H. pylori* infection, Pylera™ must be combined with a proton pump inhibitor. Thus far, use of omeprazole combined with Pylera™ has been studied. Pylera™ gained approval based on an open-label, parallel group, active-controlled, multicenter trial where *H. pylori* infected patients were randomized to receive a 10 day treatment with Pylera™ QID plus omeprazole 20mg BID or clarithromycin/amoxicillin/omeprazole 500/1000/20mg BID. After 8 weeks of therapy, the eradication rate was 92.5% for the Pylera™/omeprazole group compared to 85.7% of the clarithromycin/amoxicillin/omeprazole group. There is currently a preferred combination product on the Preferred Drug List used for *H. pylori* that contains a PPI making it more cost effective than Pylera™, since patients using Pylera™ would also have to fill a prescription for a PPI. Therefore, the current recommendation is to add Pylera™ to the Preferred Drug List as a non-preferred product.

IME Recommendation:

Preferred Drug

Non-Preferred Drug

Preferred Drug with Conditions

Recommended Drug

Non-Recommended Drug