



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Kapidex™

Common Name: Deslansoprazole

PDL Category: GI- Proton Pump Inhibitor

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Prevacid®	Preferred
Prilosec OTC™	Preferred
Protonix®	Preferred

Summary

Indications and Usage: Healing of all grades of erosive esophagitis (EE). Maintaining healing of EE. Treating heartburn associated with non-erosive gastroesophageal reflux disease (GERD).¹

Mechanism of Action: Suppresses gastric acid secretion by inhibiting the proton pump which blocks the final step of acid production.¹

Dosage Forms: Capsules: 30mg and 60mg

Recommended Dosage: Healing of EE: 60 mg once daily for up to 8 weeks. Maintenance of healed EE: 30 mg once daily for up to 6 months. Symptomatic non-erosive GERD: 30 mg once daily for 4 weeks. Hepatic impairment: Consider 30 mg maximum daily dose for patients with moderate hepatic impairment (Child-Pugh Class B). No studies were conducted in patients with severe hepatic impairment (Child-Pugh Class C).¹

Common Adverse Drug Reactions: Diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting, and flatulence.¹

Contraindications: Patients with known hypersensitivity to any component of the formulation.¹

Manufacturer: Takeda Pharmaceuticals America, Inc.

Analysis: Kapidex™ is the first proton pump inhibitor with a Dual Delayed Release (DDR) formulation designed to provide two separate releases of medication. In the studies to gain FDA approval, Kapidex™ was compared to both placebo and Prevacid®. Kapidex™ demonstrated similar efficacy of the healing of erosive esophagitis when compared to Prevacid®, although Kapidex™ was approved for use in a dose twice that of Prevacid®. In addition, the incidence of treatment-emergent adverse reactions remained lower for the Prevacid® treatment groups when compared to the Kapidex™ treatment groups in clinical trials. Preferred alternatives appear on the Preferred Drug List, which have similar clinical efficacy and are more cost effective. Some of the preferred alternatives also have an indication for pediatric use. Therefore, it is recommended that Kapidex™ be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation: Preferred Drug Recommended Drug
 Non-Preferred Drug Non-Recommended Drug
 Non-Preferred Drug with Conditions

1. Kapidex™ [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 2009.