



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Pradaxa®

Common Name: dabigatran etexilate

PDL Category: Anticoagulants

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Warfarin	Preferred

Summary

Indications and Usage: To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. ¹

Mechanism of Action: Inhibits thrombin. ¹

Dosage Forms: Capsules; 75mg and 150mg ¹

Recommended Dosage: 150mg twice daily. Dose adjustment is required for renal impairment. Recommended dose is 75mg twice daily in patients with Cr Cl 15-30ml/min. ¹

Common Adverse Drug Reactions: Bleeding and gastritis-like symptoms. ¹

Contraindications: Active pathological bleeding. ¹

Manufacturer: Boehringer Ingelheim Pharmaceuticals, Inc.

Analysis: Pradaxa® is a direct thrombin inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. In the study used to gain FDA approval, the annualized rate of life-threatening bleed was 1.5% for Pradaxa® compared to 1.8% with warfarin, however there was a significantly higher rate of major GI bleed with Pradaxa® 150mg vs warfarin. In addition, Pradaxa® significantly reduced the primary endpoint of stroke and systemic embolism as compared to warfarin. 2.2% and 3% of the Pradaxa® groups (150mg bid and 110mg bid respectively) had an event (stroke or systemic embolism) compared to 3.4% of the warfarin group. It is recommended that Pradaxa® be added to the Preferred Drug List as a non-preferred drug to verify diagnosis of use and a trial with a preferred drug resulting in poor control.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Non-Preferred Drug with Conditions	

1. Pradaxa® [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; 2010.