



## Therapeutic Class Review<sup>SM</sup>

### Cardiology: Innopran XL

November 2005

**New Product for Review:**

propranolol CR (Innopran XL<sup>®</sup>)  
[Reliant Pharmaceuticals, Inc]

**Dossier Provided by Manufacturer: Yes**

**Dossier Evaluation: 2**

- 1 - dossier w/missing components
- 2 - all components, except pharmacoeconomic model
- 3 - all components, well done

#### Executive Summary

- Propranolol has been extensively studied in hypertension, angina, migraine prophylaxis, esophageal varices, heart failure, and post-myocardial infarction.
- Innopran XL and Inderal LA both contain propranolol and are extended-release, once-daily products.
- There is no data that demonstrates differences in clinical benefits among the different propranolol products.
- No clinically relevant differences have been demonstrated among the extended-release propranolol products.
- Overall discontinuation rates are lower with the extended-release propranolol products versus the immediate-release products based on adherence data for these medications.
- Among the extended-release products, Innopran XL provides the best value.

#### Decision

- Add propranolol CR (Innopran XL) to the preferred medication list/formulary because it is an effective, low-cost alternative to Inderal LA.

## Products

<b>Drug Product</b>	<b>Date of FDA Approval</b>	<b>FDA Approved Indications</b>	<b>Dose/Route</b>	<b>Potential Off-Label Uses</b>
atenolol (generic) <sup>1,5</sup>	8/1981	hypertension, angina pectoris due to coronary atherosclerosis, acute myocardial infarction	50 to 100 mg orally daily; for angina pectoris, may increase to 200 mg daily	arrhythmias, essential tremor, anxiety, congestive heart failure, gastrointestinal bleeds, migraine prophylaxis, syncope, withdrawal symptoms
metoprolol (generic) <sup>2,5</sup>	8/1978	hypertension, angina pectoris, acute myocardial infarction	50 to 100 mg orally twice daily; may be dosed daily in hypertension; may increase to 400 mg/day in angina pectoris and 450 mg/day in hypertension	arrhythmias, essential tremor, anxiety, congestive heart failure, gastrointestinal bleeds, migraine prophylaxis, syncope, withdrawal symptoms, aggressive behavior
propranolol (generic) <sup>5</sup>	11/1967	hypertension, angina pectoris due to coronary atherosclerosis, migraine prophylaxis, hypertrophic subaortic stenosis, tremor, pheochromocytoma	80 to 320 mg orally daily in 2 to 4 divided doses	anxiety, hyperthyroidism, neuroleptic induced akathisia
propranolol CR capsule (Innopran XL <sup>®</sup> ) <sup>3,5</sup>	3/2003	hypertension	80 to 120 mg orally daily; maximum of 120 mg	angina pectoris, migraine prophylaxis, hypertrophic subaortic stenosis, arrhythmias, essential tremor, pheochromocytoma, post myocardial infarction, anxiety, hyperthyroidism, congestive heart failure, gastrointestinal bleeds, neuroleptic induced akathisia
propranolol ER capsule (Inderal <sup>®</sup> LA) <sup>4,5</sup>	4/1983	hypertension, angina pectoris due to coronary atherosclerosis, migraine prophylaxis, hypertrophic subaortic stenosis	80 to 160 mg orally daily; maximum of 640 mg for hypertension; maximum 240 to 320 mg daily for other indications	arrhythmias, essential tremor, pheochromocytoma, post myocardial infarction, anxiety, hyperthyroidism, congestive heart failure, gastrointestinal bleeds, neuroleptic induced akathisia
metoprolol ER tablet (Toprol XL) <sup>5,6</sup>	1/1992	hypertension, angina pectoris, heart failure	25 to 100 mg daily (max of 400 mg/day) 100 mg orally daily (max of 400 mg daily) 25 mg orally daily (max 200 mg/day)	arrhythmias, essential tremor, anxiety, gastrointestinal bleeds, migraine prophylaxis, syncope, withdrawal symptoms, aggressive behavior

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