



Therapeutic Class ReviewSM

Cardiology: Innopran XL

July 2005

New Product for Review:

propranolol CR (Innopran XL[®]) - Reliant Pharmaceuticals, Inc]

Dossier Provided by Manufacturer: Yes

Available Therapeutic Alternative:

Preferred/Formulary	Non-Preferred/Non-Formulary
propranolol (Inderal [®] LA) [Wyeth Pharmaceuticals]	
propranolol (generics) [various]	

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.

Conclusion

- Propranolol CR (Innopran XL) is preferred/formulary because it is an effective, low-cost alternative to Inderal LA.

Products

Drug Product	Date of FDA Approval	FDA Approved Indications	Dose/Route	AWP Cost*	Potential Off-Label Uses
atenolol (generic) ^{1,5}	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	\$1.50 to \$4 † (for 50 to 100 mg daily)	arrhythmias, essential tremor, anxiety, congestive heart failure, gastrointestinal bleeds, migraine prophylaxis, syncope, withdrawal symptoms
metoprolol (generic) ^{2,5}	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	\$1 to \$3 † (for 50 mg daily to 100 mg twice daily)	arrhythmias, essential tremor, anxiety, congestive heart failure, gastrointestinal bleeds, migraine prophylaxis, syncope, withdrawal symptoms, aggressive behavior
propranolol (generic) ⁵	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	\$6 to \$12 (for 80 mg to 120 mg daily)	anxiety, hyperthyroidism, neuroleptic induced akathisia
propranolol CR capsule (Innopran XL [®]) ^{3,5}	3/2003	hypertension	80 to 120 mg orally daily; maximum of 120 mg	\$41 (for 80 mg to 120 mg daily)	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 [®] LA) ^{4,5}	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	\$50 to \$62 (for 80 mg to 120 mg daily)	arrhythmias, essential tremor, pheochromocytoma, post myocardial infarction, anxiety, hyperthyroidism, congestive heart failure, gastrointestinal bleeds, neuroleptic induced akathisia
metoprolol ER tablet (Toprol XL) ^{5,6}	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)	\$28 to \$43 (for 25 mg to 100 mg daily)	arrhythmias, essential tremor, anxiety, gastrointestinal bleeds, migraine prophylaxis, syncope, withdrawal symptoms, aggressive behavior

*AWP (average wholesale price) based on First Data Bank as of April 2005 for 1 month of therapy.

† based on MAC (maximum allowable cost) pricing as of June 2005 for 1 month of therapy.

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