

### Drugs recently approved or pending approval

#### PROTONIX IV

Approval was granted to Wyeth-Ayerst Laboratories (Philadelphia, PA) to market Protonix IV (pantoprazole sodium) for Injection, which is indicated for short-term treatment (7 to 10 days) of gastroesophageal reflux disease (GERD) as an alternative to oral therapy in patients who are unable to continue taking Protonix Delayed-Release Tablets. A multicenter, double-blind, 2-period placebo-controlled study assessed the ability of Protonix IV to maintain gastric acid suppression in patients switched from the oral dosage form of pantoprazole to the intravenous dosage form. GERD patients (N = 65) were randomized to receive either 20 or 40 mg of oral pantoprazole once daily for 10 days (period 1) and then were switched in period 2 to either daily Protonix IV or placebo for 7 days at the same dose level. After 10 days of repeated oral administration, followed by 7 days of intravenous administration, the mean maximum acid output levels of the oral and intravenous dosage forms of Protonix 40 mg were 6.49 and 6.62 mEq/h, respectively, compared with 29.19 mEq/h in the placebo group. The mean basal acid output levels for the oral and intravenous groups of Protonix 40 mg were 0.80 and 0.53 mEq/h, respectively, compared with 4.14 mEq/h in the placebo group. The most common adverse events associated with Protonix IV are abdominal pain, chest pain, rash, and pruritus. The recommended adult dosage of Protonix IV, as an alternative to oral therapy, is 40 mg given once daily by intravenous infusion for 7 to 10 days.



#### LUMIGAN

The US Food and Drug Administration approved marketing of Lumigan (bimatoprost ophthalmic solution) 0.03% by Allergan, Inc (Irvine, CA) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are intolerant of other IOP-lowering medications or insufficiently responsive to another IOP-lowering medication. In clinical studies of 715 patients, 64% of patients receiving Lumigan once daily achieved target IOP of less than or equal to 17 mm Hg. In contrast, 37% of patients receiving timolol (another drug used to lower IOP) twice daily achieved the same target pressure. After 6 months, Lumigan produced a 33% reduction in IOP (8.1 mm Hg), compared with a 23% reduction with timolol (5.6 mm Hg). Lumigan has been reported to cause changes to pigmented tissues, including increased pigmentation and growth of eyelashes and increased pigmentation of the iris and periorbital tissue (eyelid). These changes may be

permanent. Lumigan should be administered during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus. Lumigan should not be administered while wearing contact lenses. The most frequently reported adverse events associated with Lumigan include conjunctival hyperemia, growth of eyelashes, and ocular pruritus. The recommended dosage of Lumigan is 1 drop in the affected eye(s) once daily in the evening. The dosage should not exceed once daily, since it has been shown that more frequent administration may decrease the IOP-lowering effect of the drug.

#### TRAVATAN

Alcon Laboratories, Inc (Fort Worth, TX) received approval to market Travatan (travoprost ophthalmic solution) 0.004% for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension who are intolerant of or inadequately treated by using other IOP-lowering medications. Travatan was studied in 8 well-controlled clinical trials involving more than 1800 subjects worldwide. Patients with open-angle glaucoma or ocular hypertension and baseline IOP of 25 to 27 mm Hg who were treated with Travatan once daily in the evening demonstrated 7- to 8-mm Hg reductions in IOP. When used adjunctively with timolol 0.5%, Travatan produced a 7-mm Hg reduction of IOP in patients not controlled by timolol 0.5% alone. In subgroup analyses of these studies, mean IOP reduction in black patients was up to 1.8 mm Hg greater than in non-black patients. Travatan should not be used by pregnant women or by women attempting to become pregnant. Travatan has been reported to cause changes to pigmented tissues, including increased pigmentation of the iris and periorbital tissue (eyelid) and increased pigmentation and growth of eyelashes. These changes may be permanent. Travatan should not be administered while wearing contact lenses. The most common ocular adverse events observed in clinical studies with Travatan include ocular hyperemia, decreased visual acuity, eye discomfort, and pruritus. The recommended dosage of Travatan is 1 drop in the affected eye(s) once daily in the evening. The dosage of Travatan should not exceed once daily, since it has been shown that more frequent administration may decrease its IOP-lowering effect.

*Compiled from press reports and pharmaceutical company press releases. For more information, contact Jennifer Vander Bush, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*

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