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October 2005

IMPORTANT ALERT REGARDING MEDICATION ERRORS TEGRETOL® and TEGRETOL-XR® and TOPROL-XL®

Dear Health Care Provider:

Novartis Pharmaceuticals Corporation would like to inform you of reports it received of medication errors involving confusion between **Tegretol**® (carbamazepine) or **Tegretol-XR**® (carbamazepine extended-release), indicated for the treatment of partial, secondarily generalized and generalized tonic-clonic seizures and for treatment of pain associated with trigeminal neuralgia, and **Toprol-XL**® (metoprolol succinate) extended release tablets, a product of AstraZeneca, indicated for the treatment of hypertension, long-term treatment of angina pectoris, and heart failure (New York Heart Association Class II or III). These reports include instances where Tegretol or Tegretol-XR was incorrectly administered to patients instead of Toprol-XL and **vice versa**.

A few cases of adverse events have been reported to Novartis as a result of non-administration of the intended medication and/or exposure to the wrong medication. In these cases, seizures and elevated blood pressure have been reported.

The products involved in these medication errors are indicated for the treatment of serious medical conditions. Erroneous administration, or delay in administration of the prescribed medications of Toprol-XL, Tegretol or Tegretol-XR may cause serious health consequences.

Toprol-XL has a boxed warning against abrupt cessation of therapy in patients with ischemic heart disease, as it may precipitate angina or myocardial infarction.

Tegretol has a boxed warning regarding aplastic anemia and agranulocytosis.

Tegretol-XR and Tegretol have a warning that, as with all antiepileptic drugs, they should be withdrawn gradually to minimize the potential of increased seizure frequency.

Tegretol tablets are single-scored tablets with the following characteristics:

Tablet	Color/Shape	Engraving	Sample
100 mg	Red speckled, Pink Round	"TEGRETOL" on one side, "52" twice on the scored side	
200 mg	Pink Capsule-shaped	"TEGRETOL" on one side, "27" twice on the scored side	

Tegretol XR tablets are coated, round tablets with the following characteristics:

Tablet	Color	Engraving	Sample
100 mg	Yellow	"T" on one side, "100 mg" on the other side	
200 mg	Pink	"T" on one side, "200 mg" on the other side	
400 mg	Brown	"T" on one side, "400 mg" on the other side	

TOPROL-XL® (metoprolol succinate) extended release tablets are available as white, biconvex, film-coated, and scored tablets with the following characteristics:

Tablet	Shape	Engraving	Sample
25 mg*	Oval	A ß	
50 mg	Round	A mo	
100 mg	Round	A ms	
200 mg	Oval	A my	

Your assistance is requested in clearly communicating oral and written prescriptions for these products to help avoid future dispensing errors. Steps you can take to decrease the potential for medication errors include printing legible prescriptions that include the brand and generic names with indication, and discussion of indications and proper use of medications with patients.

To help minimize the risk for dispensing errors, Novartis Pharmaceuticals Corporation will also be notifying pharmacists as to the potential for confusion.

Healthcare professionals who become aware of any medication errors involving Tegretol or Tegretol-XR should report them immediately to Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, New Jersey 07936 or by phone (888) NOW-NOVARTIS or (888-669-6682) or the internet at http://www.novartis.com/contact/en/index.shtml.

Alternatively, this information may be reported to the FDA's MedWatch Reporting System by phone at 1-800-FDA-1088, by fax 1-800-FDA-0178, by mail using the Form 3500 at MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20857 or the internet at http://www.accessdata.FDA.gov/scripts/medwatch, or to the USP Medication Error Reporting Program in cooperation with the Institute for Safe Medication Practices at 1-800-23ERROR.

Tegretol® (carbamazepine) is indicated as first-line monotherapy for the treatment of partial, secondarily generalized, and generalized tonic-clonic seizures and for treatment of pain associated with trigeminal neuralgia. The safety of carbamazepine in children has systematically been studied in clinical trials up to 6 months, and longer-term data is not available. The most frequently observed adverse reactions, particularly during the initial phases of therapy, are dizziness, drowsiness, unsteadiness, nausea, and vomiting. Although reports of transient or persistent decreased platelet or white blood cell counts are not uncommon in association with the uses of Tegretol, the vast majority of cases of leucopenia have not progressed to the more serious conditions of aplastic anemia or agranulocytosis. When initiating therapy, obtain complete pretreatment hematologic testing as a baseline.

Also, please refer to the enclosed full Prescribing Information for Tegretol and Tegretol-XR, or visit http://www.pharma.us.novartis.com/product/pi.jsp

Sincerely,

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