



## Medication Access Program Newsletter

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*The Medication Access Program (MAP) is a statewide program for solid-organ transplant recipients in Georgia that offers information about medication assistance programs and helps with the enrollment into these programs.*

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## Updates on Patient Assistance Programs

Over the last two years, there have been many changes concerning medications offered by patient assistance programs from pharmaceutical companies. For example, **Myfortic<sup>®</sup>** (mycophenolate acid), manufactured by Novartis, has several programs that provide assistance with this medication. For more information contact Novartis at 1-800-277-2254. **Azasan<sup>®</sup>** (azathioprine), manufactured by **Salix Pharmaceuticals, Inc.**, is also available through an assistance program. For questions regarding the program or application, please call Salix Pharmaceuticals Patient Assistance Program at 1-866-282-6563. The following drugs are no longer available through a patient assistance program: **Pepcid<sup>®</sup>**, **Adalat<sup>®</sup>**, **Bextra<sup>®</sup>**, however **Vioxx<sup>®</sup>**, **Pepcid<sup>®</sup>** and **Adalat<sup>®</sup>** have a generic equivalent that is available. Patients may also take advantage of patient assistance programs that provide qualified low-income individuals and families with access to generic medications. More than 50 generic medications that treat a wide range of conditions including diabetes, asthma, heart disease, and depression are available. For more information on the medications available and applications contact **Xubex Pharmaceuticals Services** at 1-866-699-8239 or **Rx Outreach (Express Scripts Specialty Distribution Services, Inc.)** at 1-800-769-3880. **CellCept<sup>®</sup>** (mycophenolate mofetil), offered by Roche CellCept Patient Assistance Program, now ships a 90-day supply of medication, instead of a 60-day supply, however, no refills are allowed and a new re-qualification form must be completed and signed by both the physician and patient. For additional questions about any of the above programs or programs that are not listed in this article, please feel free to contact MAP at (706) 721-0131.



## New Medications: Ketek<sup>®</sup> (*telithromycin*)

Ketek<sup>®</sup> (telithromycin), manufactured by Aventis pharmaceuticals, is the first antibiotic from the ketolide class. Telithromycin, a derivative from erythromycin (a macrolide antibiotic), is indicated for the oral treatment of mild to moderate community-acquired pneumonia (CAP), acute exacerbations of chronic bronchitis (AECB), and acute bacterial sinusitis (ABS) in patients age 18 years and older.<sup>1,2</sup>

Telithromycin inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit. With an absolute bioavailability of 57%, telithromycin is rapidly absorbed by the gastrointestinal (GI) tract. Absorption is not affected by food. Peak concentrations are achieved in approximately one hour. Steady state plasma levels are reached in 2 to 3 days with continued dosing. The half-life of telithromycin is 10 hours.<sup>1,2</sup>

The most common side effects of telithromycin include GI disturbances, which are characterized by diarrhea, nausea, and vomiting. Other side effects include visual disturbances, which are characterized by blurred vision, diplopia, and difficulty in focusing. In clinical trials, visual disturbances occurred in approximately 1% of patients, with women less than 40 years age having the highest incidence at 2%.<sup>1,2</sup>

Due to its characteristics as a substrate and potent inhibitor of CYP3A4

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isoenzyme, Ketek® has the potential for many drug interactions. It can increase the serum concentrations of midazolam (Versed®), ergot alkaloids, ritonavir (Norvir®), sirolimus (Rapamune®), and tacrolimus (Prograf®). This antibiotic can also cause increased serum levels of metoprolol and digoxin. In addition, itraconazole (Sporanox®) and ketoconazole (Nizoral®) inhibit metabolism of telithromycin, therefore causing an increase in serum concentrations of telithromycin. Other drugs that affect the metabolism of Ketek® include metabolic inducers such as rifampin, carbamazepine, and phenytoin. The combination of rifampin and telithromycin should be avoided. Co-administration of theophylline (Theodur®) and telithromycin may increase the adverse GI effects of telithromycin, therefore, these medications should be taken at least one hour apart. The serum concentration and absorption of sotalol (Betapace®) are decreased when used with telithromycin.<sup>1,2</sup>

The use of Ketek® is contraindicated in patients with an allergy to macrolides. Ketek® should be used with caution when administered with other drugs that cause a prolongation of the QT interval. In addition, Ketek® should be avoided in patients with myasthenia gravis due to the potential for life-threatening respiratory failure.<sup>1,2</sup>

Ketek® is available as a 400 mg tablet. The recommended dose is 800 mg once daily for 7 to 10 days for CAP and 5 days for AECB or ABS. Dosing in patients with severe renal insufficiency has not been established, and there is no dosage adjustment required in patients with hepatic insufficiency.<sup>1,2</sup>

Patients should be advised about possible visual disturbances that may occur while on telithromycin therapy, and should contact their physician if these disturbances disrupt daily functions. Patients should also be informed to take two 400 mg tablets at the same time, and not to divide the dosing during the day. Finally, patients who are currently taking atorvastatin

(Lipitor®), simvastatin (Zocor®), or lovastatin (Mevacor®) should be advised to discontinue use while taking telithromycin, since telithromycin may inhibit metabolism of these drugs through the cytochrome P450 system. Aventis does not currently offer a patient assistance program for Ketek®.

1. The Medical Letter. Volume 46 (Issue 1189). August 16, 2004.
2. Ketek® (telithromycin) Prescribing Information. Accessed June 23, 2005. Available at: [http://www.aventis-us.com/PIs/ketek\\_TXT.html](http://www.aventis-us.com/PIs/ketek_TXT.html) Accessed June 23, 2005.

### Equetro™ (carbamazepine)

Equetro™, extended-release carbamazepine, was approved on December 10, 2004 by the FDA for treatment of acute mania and mixed episodes of bipolar disorder. The same formulation, manufactured by Shire US Inc., has been marketed as Carbatrol® for the treatment of epilepsy since 1997.<sup>1</sup>

Carbamazepine is associated with many adverse effects, which commonly include dizziness, nausea, somnolence, and headache. Aplastic anemia and agranulocytosis, as well as Stevens-Johnson syndrome, have rarely occurred with carbamazepine use. Increases in serum cholesterol concentrations, hyponatremia, hypertension, hypotension, diplopia, and cardiac conduction abnormalities have also been reported as adverse effects. In pregnant women, carbamazepine has been associated with neural tube defects, including spina bifida in about 1% of live births.

Carbamazepine is an iminostilbene derivative chemically related to the tricyclic antidepressants whose mechanism of action is unknown but appears to reduce polysynaptic responses and block post-tetanic potentiation. Carbamazepine is 76% bound to plasma proteins. Plasma levels may range from 0.5 to 25 mcg/mL with no apparent relationship to the daily intake but the usual therapeutic levels are between 4 and 12 mcg/mL. After administration, 72% is excreted in the

urine and 28% in the feces. Urinary products are composed largely of hydroxylated and conjugated metabolites, with only 3% as unchanged drug.

Because carbamazepine is extensively metabolized by the CYP3A4 enzymes in the liver, toxicity can develop with concomitant use of potent 3A4 inhibitors such as itraconazole (Sporanox®), which will increase serum levels of Equetro™. Rifampin and other inducers of CYP3A4 can decrease the concentrations of carbamazepine. Other interactions can occur including decreased effectiveness of warfarin and oral contraceptives due to carbamazepine inducing 3A4 and 1A2 and potentially decreasing the other drugs serum concentrations.

The recommended starting dose of Equetro™ for adults with acute mania is 200 mg of extended release twice a day. The dose may be increased by 200 mg daily up to 1600 mg daily. The drug is supplied as 100-, 200-, and 300 mg capsules containing immediate-release, extended-release, and enteric-release beads, which should never be chewed or crushed but can be opened and sprinkled over food.

For information about Shire's patient assistance program for Carbatrol®, you can contact the Shire US patient assistance program at 1-866-325-8224. You may also call the MAP office at (706) 721-0131.

1. The Medical Letter. Volume 47 (Issue 1240). March 28, 2005.

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The MAP newsletter is published quarterly to present topics of interest to the transplant community. If you would like to submit material to be considered for publication in the newsletter, please contact MAP at:  
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