



The Procter & Gamble Company
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News Release

NEW STUDY SUGGESTS NUMBER OF PILLS NOT A FACTOR WHEN IT COMES TO DAILY ADHERENCE TO MEDICATION

CINCINNATI, JUNE 5, 2007 – There is no correlation between the daily number of pills a patient is prescribed to take and how well a patient will adhere to a dosing regimen, suggests a new study presented recently at the 19th Annual Meeting of the Academy of Managed Care Pharmacy (AMCP) held in San Diego (April 11-14). The large-scale study looked at patients taking a variety of high blood pressure medicines, specifically calcium channel blockers (CCBs), and provides more supportive evidence that adherence to prescribed medication is influenced by a multitude of factors. The study specifically examined dosing regimen to see if there was a relationship between that factor and adherence in patients with a co-payment of at least \$20.

Poor adherence to medication is a recognized medical problem in the U.S., costing an estimated \$100 billion a year.ⁱ Previous studies have found that issues contributing to poor adherence to medication are multifactorial.ⁱⁱ According to the study's lead author, Diana Brixner, Ph.D., University of Utah Pharmacotherapy Outcomes Research Center, these new data can help emphasize to health care providers the importance of discussing various components of medication adherence with patients with chronic illnesses.

"We know from past research that chronic illnesses like hypertension or ulcerative colitis worsen when patients fail to take medication as prescribed – and this puts additional burdens not only on patients, but the health care system," says Brixner. "Data like these demonstrate that the influences on adherence are multi-factorial, and therefore it is a critical topic for all involved in the healthcare process to bring up to patients who take medication long-term."

About the Study

The one-year, retrospective cohort study analyzed over 19,000 records of health service reimbursement from U.S. health plans within the Medstat MarketScan database, and looked at the

prescription refill rates of different CCBs formulated for different daily dosing regimens (once daily, twice daily and three times daily dosing). All patients were 18 years of age and older and were patients with a physician-visit for high blood pressure. Several CCBs are available in different versions which have various defined dosing instructions (once daily to three times daily). CCBs with a co-pay \geq \$20 were included in the analysis. The percentage of patients persisting on their prescriptions was measured at the end of one year. Persistence at 12 months was defined by looking 12 months, +/- 30 days from index date and seeing if the subject had a refill.

The study found that the range of persistence for the once daily drugs varied widely from 17% to 59%. There was no noticeable difference in drugs intended to be given once daily, twice daily, and three times daily. The twice daily/three times daily 1-year persistence rates ranged from 44% to 58%.

“Despite the perception that dosing regimen is a primary factor influencing medication adherence, our study showed that this was not the case,” said co-author Simon Magowan, M.D., of Procter & Gamble Pharmaceuticals, the study’s sponsor. “This and other studies have suggested that reasons for non-adherence are often patient-specific and multifaceted.”

One such study was presented at last year’s annual scientific meeting of the American College of Gastroenterology by Sunanda Kane, M.D., University of Chicago, and found that while there is a steady decline in refill rates for 5-ASAs for ulcerative colitis, drug formulation and the number of pills taken each day did not appear to affect long-term adherence.

In addition to its well-known consumer brands, P&G develops and markets a gastrointestinal platform that extends across pharmaceutical and over-the-counter brands. One of these brands is Asacol® (mesalamine) Delayed-Release Tablets, available by prescription only, which is currently celebrating 15 years of trusted therapy. Asacol is the No. 1 most-prescribed 5-ASA therapy for ulcerative colitis (UC), a form of inflammatory bowel disease (IBD).ⁱⁱⁱ Additional information about Asacol can be found by visiting www.Asacol.com.

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About Ulcerative Colitis

UC involves inflammation of the lining of the colon and rectum. It varies in clinical severity with patients having mild, moderate or severe disease. Treatment depends on the extent and severity of disease.

UC causes flares followed by periods of remission. During a flare, in which the rectum or colon become inflamed, people experience symptoms such as diarrhea, rectal bleeding, abdominal cramping and an urgent need to go to the bathroom. Flares can vary in duration and intensity. While UC is a lifelong condition, medication may help control flares.

UC affects people of all ages, but is often diagnosed during early adulthood. The causes of this condition are unknown, but may involve heredity, infection or the immune system.

About Asacol[®] (mesalamine) Delayed-Release Tablets 400 mg

Asacol is indicated for the treatment of mildly to moderately active UC (the indicated dosage is two 400 mg tablets tid for 6 weeks) and for the maintenance of remission of UC (the indicated dosage is 1.6 g/day in divided doses).

Asacol was well-tolerated in clinical studies. Overall, the incidence of adverse events with Asacol was comparable to placebo. In pivotal clinical studies of mildly to moderately active UC, the most frequent adverse events reported for Asacol and placebo, respectively, were headache (35% vs. 36%), abdominal pain (18% vs. 14%), eructation (16% vs. 15%), pain (14% vs. 8%) and nausea (13% vs. 15%); for the maintenance of remission of UC, the most frequent adverse events were headache (50% vs. 50%), rhinitis (42% vs. 36%), diarrhea (35% vs. 50%), abdominal pain (32% vs. 44%) and flatulence (24% vs. 30%).

Asacol is contraindicated in patients with hypersensitivity to salicylates. Caution should be exercised when using Asacol in patients with known renal dysfunction or history of renal disease. It is recommended that all patients have an evaluation of renal function prior to initiation of Asacol tablets and periodically while on Asacol therapy. Serious adverse events may occur with Asacol. Please visit <http://www.pgpharma.com/pi/US-Asacol.pdf> for full prescribing information.

About Procter & Gamble (NYSE:PG)

Three billion times a day, P&G brands touch the lives of people around the world. The company has one of the strongest portfolios of trusted, quality, leadership brands, including Actonel[®], Asacol[®], Enablex[®], Prilosec OTC[®], Metamucil[®], Fibersure[®], Align[®], Pepto-Bismol[®], Vicks[®], ThermaCare[®], PUR[®], Crest[®] and Oral-B[®]. The P&G community consists of over 135,000 employees working in over 80 countries worldwide. Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.

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ⁱ O’Conner, P, Improving Medication Adherence, Archives of Internal Medicine 2006, 166: 1802-1804.

ⁱⁱ Osterberg, L, Adherence to Medication, New England Journal of Medicine 2005, 353;5.

ⁱⁱⁱ Data on file: IMS National Prescription Audit, 12 months ending May 2006.