



News Release

The Procter & Gamble Company  
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Cincinnati, OH 45202

**PROCTER & GAMBLE PHARMACEUTICALS LAUNCHES ASACOL<sup>®</sup> HD (MESALAMINE)  
DELAYED-RELEASE TABLETS**

*Asacol HD offers moderately active UC patients a new treatment option for managing their flares*

Cincinnati, Ohio, July 7, 2009 – Procter & Gamble Pharmaceuticals (P&GP) announced today the availability of Asacol HD (mesalamine) delayed-release tablets, which are indicated for the treatment of moderately active ulcerative colitis (UC), a form of inflammatory bowel disease. UC involves inflammation of the lining of the colon and rectum and is typically characterized by flares followed by periods of remission. Moderately active UC is characterized by tougher symptoms than mildly active UC. Asacol HD is proven to help treat these tougher flares of moderately active UC. Asacol HD was approved by the U.S. Food and Drug Administration (FDA) based on evaluations from the ASCEND studies [Assessing the Safety and Clinical Efficacy of a New Dose of 5-ASA (4.8 g/day 800 mg tablet)].

In six-week clinical studies of moderately active UC flares, Asacol HD at 4.8 g/day helped many patients reduce their UC symptoms, including number of bowel movements and rectal bleeding, for some as early as three weeks. Asacol HD decreased the number of trips to the bathroom (i.e., number of bowel movements) in approximately three out of four of patients by six weeks and decreased rectal bleeding for approximately 80 percent of patients by six weeks. Patients should discuss their experiences with Asacol HD with a physician, as their individual results may vary.

“In six-week clinical trials of moderately active UC, Asacol HD helped reduce rectal bleeding and stool frequency, without the use of steroids. These encouraging results help support Asacol HD as an effective therapy in patients with moderately active UC,” said Stephen B. Hanauer, M.D., Chief of Gastroenterology, Hepatology and Nutrition at the University of Chicago Medical Center. “Every patient’s disease is different and requires a personal approach to treatment. A course of treatment that is right for one patient may not be right for another. Patients should speak with their doctors to determine the course of therapy that is best for them.”

P&GP has been a leader in UC research and education through support of professional UC programs and research grants. P&GP is also the maker of Asacol<sup>®</sup> (mesalamine) 400 mg delayed-release tablets, the number one most-prescribed oral 5-aminosalicylic acid (5-ASA) therapy.\* More than 20 million prescriptions have been written for Asacol since its FDA approval and U.S. launch in 1992.† Physicians have relied on Asacol as a trusted UC therapy for more than 17 years. Asacol HD is the newest addition to P&GP's GI portfolio.

"Procter & Gamble is delighted to introduce Asacol HD to the Asacol franchise. This new addition will further help UC patients get their symptoms under control so that their lives can be more predictable," said Dan Hecht, General Manager for P&G Pharmaceuticals, North America. "This addition to P&G's robust portfolio of gastrointestinal therapies underscores P&G's continued commitment to developing innovative ways to improve the lives of millions of people that struggle with GI conditions every day."

If for any reason a patient is dissatisfied with the first course of therapy, P&GP will refund the receipted cost of the original prescription. Receipted cost includes only the amount actually paid by the patient. P&GP will not refund costs covered by third party payers, including Medicaid. Call 1-800-448-4878 for more information.

### **Detailed Clinical Data for Asacol HD in Moderately Active UC**

The efficacy and safety of Asacol HD was evaluated in the ASCEND studies.

The primary endpoint of the ASCEND II and III studies was overall improvement at six weeks, which was determined by the Physician's Global Assessment (PGA) which encompassed the clinical assessments of rectal bleeding, stool frequency and sigmoidoscopy findings. The Patient's Functional Assessment (PFA) was also included in ASCEND II.

In ASCEND III, 70 percent of patients (n=273/389) achieved overall improvement with Asacol HD at 4.8 g/day as compared to 66 percent of patients (n=251/383) who took Asacol 400 mg tablets at 2.4 g/day.<sup>1</sup> In ASCEND II, 72 percent of patients (n=89/124) achieved overall improvement with Asacol HD at 4.8 g/day at six weeks, as compared to 59 percent of patients

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\* Based on total prescription share data. This information is an estimate derived from the use of information under license from IMS National Prescription Data for the 12 month period ending December 2008. IMS expressly reserves all rights, including rights of copying, distribution and republication.

† IMS national prescription data from 1992-July 2006.

(n=77/130) who took Asacol 400 mg tablets at 2.4 g/day.<sup>1,2</sup> One Asacol HD 800 mg tablet has not been shown to be bioequivalent to two Asacol 400 mg tablets.

In addition, Asacol HD at 4.8 g/day demonstrated rapid improvement in rectal bleeding and stool frequency. At three weeks, rectal bleeding improved in 78 percent and 75 percent of the patients in the ASCEND III and ASCEND II studies, respectively. At six weeks, 84 percent of the patients taking Asacol HD at 4.8 g/day in ASCEND III and 79 percent of patients in ASCEND II experienced improvements in rectal bleeding.<sup>1,2</sup>

At three weeks, improvement of stool frequency was achieved by 76 percent and 64 percent of patients taking Asacol HD at 4.8 g/day in the ASCEND III and ASCEND II studies, respectively. At six weeks, the percentage of patients with improved stool frequency was 79 percent in ASCEND III and 74 percent in ASCEND II.<sup>1,2</sup>

### **About Ulcerative Colitis (UC)**

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 and/or the immune system.

### **About Asacol and Asacol HD**

Asacol is indicated for the treatment of **mildly to moderately active** UC and for the maintenance of remission of UC. The recommended dosage for active UC is two 400 mg tablets TID, with or without food, for a total daily dose of 2.4 g for 6 weeks. For the maintenance of remission of UC, the recommended dosage is 1.6 g/day in divided doses.

Asacol HD is indicated for the treatment of **moderately active** UC. The recommended dose in adults is two 800 mg tablets TID, with or without food, for a total daily dose of 4.8 g. The safety and effectiveness of Asacol HD beyond 6 weeks has not been established.

In clinical trials, Asacol and Asacol HD were generally well-tolerated. The most common adverse reactions reported in patients treated with Asacol and Asacol HD were nausea, diarrhea, abdominal pain, eructation, flatulence, exacerbation of UC, headache, rhinitis, nasopharyngitis and pain.

Asacol and Asacol HD are contraindicated in patients with hypersensitivity to salicylates. Caution should be exercised when using these products 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 and periodically while on Asacol or Asacol HD therapy. Acute exacerbation of colitis symptoms can also occur. Caution should be exercised when administering Asacol or Asacol HD to patients with liver disease. Serious adverse events may occur with Asacol or Asacol HD.

Please visit <http://www.asacol.com/pdf/us-asacol.pdf> for Asacol Full Prescribing Information and <http://www.AsacolHD.com> for Asacol HD Full Prescribing Information.

### **About Procter & Gamble (NYSE:PG)**

Three billion times a day, P&G brands touch the lives of people around the world. P&G has one of the strongest portfolios of trusted, quality, leadership brands, including Actonel<sup>®</sup> (risedronate sodium) tablets, Asacol<sup>®</sup> (mesalamine) delayed-release tablets, Asacol<sup>®</sup> HD (mesalamine) delayed-release tablets, Enablex<sup>®</sup> (darifenacin) extended release tablets, Prilosec OTC<sup>®</sup>, Align<sup>®</sup>, Metamucil<sup>®</sup>, Fibersure<sup>®</sup>, Pepto-Bismol<sup>®</sup>, Vicks<sup>®</sup>, PUR<sup>®</sup>, Crest<sup>®</sup> and Oral-B<sup>®</sup>. The P&G community consists of more than 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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<sup>1</sup> Asacol HD Package Insert (April 2009)

<sup>2</sup> Hanauer SB et al. Am J Gastroenterol 2005; 100: 2478-2485.