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AXCAN PHARMA™—DELIVERING THERAPIES THAT IMPROVE SURVIVAL AND ENHANCE THE QUALITY OF LIFE FOR GASTROINTESTINAL PATIENTS

Although the etiology of most gastrointestinal (GI) diseases remains elusive, one specialty pharmaceutical company has worked for more than two decades to bring about unparalleled therapies, products and specialized programs for GI patients and their caregivers. **Axcan Pharma**™ (Birmingham, AL), has a single, well-defined mission: To improve the quality of care and treatment of patients suffering from GI diseases and related disorders. In addition to marketing more than 40 GI products, Axcan's global operation carries out research, development, and the acquisition of new products for marketing approval.

URSO Forte™ (Ursodiol Tablets USP) 500 mg

There is much agreement in the GI community that early detection of primary biliary cirrhosis (PBC) results in greatly reduced mortality and improved quality of life. More than ten years of clinical studies have confirmed the efficacy and safety of **URSO Forte** and **URSO 250®** in delaying the progression of PBC, normalizing liver function tests, decreasing the incidence of esophageal varices by 60%, and significantly improving transplant-free survival. Clinical data (*1*) continues to support the finding that early detection and rigorous treatment with ursodiol results in long-term mortality of non-cirrhotic patients that closely mirrors that of the general population. Additionally, URSO Forte and URSO 250 remain the only ursodiols approved by the FDA for patients with PBC. This patient-friendly therapy dramatically improves survival *essentially without side effects*. Studies report side effects in less than 5% of patients, and drug compatibility with most background therapies (*1*).

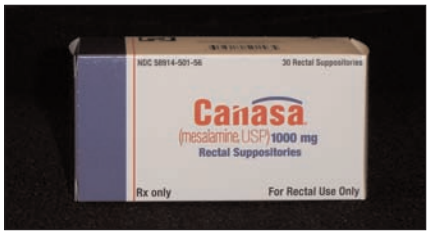
"Patient compliance with URSO® is excellent," reports Kris Kowdley, MD, FACP and Professor of Medicine at the University of Washington School of Medicine (Seattle, WA). "Symptoms at diagnosis are fatigue and itching, which typically improve quickly with correct dosing of URSO Forte." Dr. Kowdley stressed the importance of correct dosing to achieve therapeutic benefits: "Precise dosing and the improved bio-availability of URSO should be emphasized to health care providers." Studies (*1*) have shown that milligram per milligram, the bioavailability of ursodiol capsules is about two-thirds that of the URSO tablets. Additionally, Actigall and its generics are not approved for PBC treatment. The recommended adult dosage for URSO Forte and URSO 250 in the treatment of PBC is 13-15mg/kg/day administered in two to four divided doses with food. URSO Forte offers the convenience of the highest strength in ursodiol—requiring fewer tablets per day.

In a 2004 paper (*2*), by Cynthia Levy, MD, and Paul Angulo, MD, of the Mayo Medical

School in Rochester, MN, the authors analyzed the clinical data on the treatment of PBC, and reported that: "Patients with PBC not requiring liver transplantation should be treated with UDCA [ursodiol] at the standard dose of 13-15mg/kg/daily." Additionally, their finding confirmed that patient compliance with long-term correct dosing was excellent.

CANASA® (mesalamine USP) 1000 mg Rectal Suppositories: Rapid, Well-Tolerated Relief for Ulcerative Proctitis Patients

With an increasing global prevalence of ulcerative proctitis (UP), improved therapies are an essential evolution. "Patients and physicians have to be educated that the mesalamine suppository really *is* patient-friendly," says Miguel Regueiro, MD, Associate Professor of Medicine at the University of Pittsburgh Medical Center, adding that the biggest *advantage* of **CANASA** 1000 mg is excellent patient compliance. "The once-daily dosing is a real positive; most of my patients use the suppository at bedtime." Additionally, Dr. Regueiro is dual Co-Director of the Inflammatory Bowel Disease Center and the GI, Hepatology and Nutrition Fellowship at PUH, and has recently authored a paper (*3*) on ulcerative proctitis in the *Journal of Clinical Gastroenterology*. In his article Dr. Regueiro asserts: "Despite the benefit of topical therapy, there appears to be a stigma among health care providers and patients that this is invasive and will be difficult to use. Evidence-based data show that topical 5-ASA therapy is highly efficacious for ulcerative proctitis with an acceptable compliance profile."



With the convenience of higher dosing strength in a once-daily dosing, CANASA 1000 mg also has the benefit of reach—20cm into the rectal vault. Because suppositories work directly on the area involved, they have been shown to be the *most rapid and effective* therapy in treating ulcerative proctitis. CANASA 1000 mg Suppositories quickly stop rectal bleeding within one week of therapy; significantly reduce stool frequency, diarrhea and tenesmus within two weeks; and reduce the urgency associated with tenesmus. And because there is minimal systemic 5-ASA absorption, CANASA 1000 mg Suppositories typically have a side effect profile similar to placebo. The usual regimen is three to six weeks depending on symptoms and sigmoidoscopy findings. Further studies with CANASA 500 mg Suppositories suggested that CANASA Suppositories will delay relapse after the six-week short-term treatment, and that maintenance therapy greatly improves the course of the disease. "In my experience, the use of a combination of oral 5-ASA and intermittent topical ASA is a good strategy for maintaining remission of UP," confirms Dr. Regueiro, who adds that CANASA 1000 mg is the only FDA approved once-daily suppository available.

At a time when patients are less willing to settle for a compromised quality of life, Axcan Pharma™ is a frontrunner in advancing unmatched therapeutics with precision delivery and dosing.

For more information concerning Axcan Pharma™ and its products, call 1-800-472-2634; contact an Axcan representative at DDW booth #1443; or visit the company's Web site at www.axcan.com.

References:

1. Data on file at Axcan Pharma.
2. Levy, C, MD, and, Angulo, P, MD. *Am J Gastroenterol* 2004;269-70.
3. Regueiro, MD, MD. *J Clin Gastroenterol* 2004;38:733-40.