Press release, 14 September 2007

FDA approves SOMA 250 mg

The Food and Drug Administration (FDA) has approved SOMA (carisoprodol) 250 mg as a new recommended dose. SOMA is a skeletal muscle relaxant, indicated for treatment of painful musculoskeletal conditions such as backache.

SOMA is a well-established brand in the US and the substance carisoprodol, generates around 10 million prescriptions per year. SOMA 250 mg is now the only available low-dose treatment of carisoprodol that can offer similar efficacy as SOMA 350 mg but with a more favourable tolerability profile. SOMA 250mg is granted a minimum 3 year exclusivity period in the US. The launch will start immediately.

The FDA approval of SOMA 250 mg was based on the results from two randomized, double-blind, placebo-controlled, multi-site parallel group studies which have been ongoing for several years and included more than 1,300 patients. “The clinical benefits of SOMA 250 mg are in line with current treatment strategies for back pain which focuses on helping patients to return to normal physical activity as quickly as possible, “said Lee Ralph, M.D., Assistant Clinical Professor, Department of Family and Preventative Medicine, University of California, San Diego, LaJolla; physician partner, San Diego Sports Medicine and Family Health Center; and a lead author and investigator for the SOMA 250 mg clinical trials. “I look forward to offering my patients SOMA 250 mg as data indicates that it can help relieve discomfort from acute backache.”

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