

## FDA Approves Generic Celebrex

May 30, 2014—The FDA has approved Teva and Mylan Pharmaceuticals to market the first generic versions of Celebrex (celecoxib). Teva received approval to market all available strengths (50mg, 100mg, 200mg and 400mg) with exclusivity of 180 days for the 100mg, 200mg and 400mg strengths. For those 180 days Mylan Pharmaceuticals will only market celecoxib 50mg.<sup>1</sup> In order for a company to apply for approval from the FDA to market a generic product they must submit an abbreviated new drug application (ANDA) and must prove the drug contains the same active ingredients as the brand name product, however, inactive ingredients may vary. The generic drugs must be identical in strength, dosage form, and route of administration, have the same indications, be bioequivalent, meet the same batch requirements for identity, strength, purity, and quality and be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for brand name products.<sup>2</sup>

Celecoxib is an NSAID, available in capsule form and is indicated for ankylosing spondylitis, juvenile rheumatoid arthritis, osteoarthritis, rheumatoid arthritis, acute pain, and primary dysmenorrhea.<sup>3,4</sup> Like all NSAIDs, celecoxib carries black box warnings for both cardiovascular (CV) and gastrointestinal (GI) risks. The CV warning states it may cause an increased risk of serious CV thrombotic events, MI and stroke, which can be fatal. This risk may be increased with duration of use. Patients with CV disease or risk factors for CV disease may be at greater risk.<sup>5</sup> The GI warning states it may cause an increased risk of serious GI adverse events including bleeding, ulceration and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at a greater risk for serious GI events.<sup>5</sup> Celecoxib is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.<sup>5</sup> Celecoxib is not recommended in patients with severe hepatic or renal impairment and the dose should be reduced by 50% in moderate hepatic insufficiency.<sup>3-5</sup> Celecoxib is a pregnancy category C up to 30 weeks gestation then becomes a category D.<sup>3-5</sup> Like all NSAIDs celecoxib requires a medication guide to be dispensed to the patient each time they pick up their medication. Medication guides contain FDA-approved information that can help patients avoid serious adverse events.

### References:

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3. Celecoxib. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed June 22, 2014
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