AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

FDA Approves Inflectra

April 5, 2016

The U.S. Food and Drug Administration (FDA) approved Inflectra (infliximab-dyyb) for multiple indications. Inflectra is administered by intravenous infusion. This is the second biosimilar approved by the FDA. Inflectra is biosimilar to Janssen Biotech, Inc.'s Remicade (infliximab), which was originally licensed in 1998.

Inflectra is approved and can be prescribed by a health care professional for the treatment of:

- Adult patients and pediatric patients (ages six years and older) with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy;
- Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy;
- Patients with moderately to severely active rheumatoid arthritis in combination with methotrexate;
- Patients with active ankylosing spondylitis (arthritis of the spine);
- Patients with active psoriatic arthritis;
- Adult patients with chronic severe plaque psoriasis.

The most common side effects of Inflectra include respiratory infections, such as sinus infections and sore throat, headache, coughing and stomach pain. Infusion reactions can happen up to two hours after an infusion. Symptoms of infusion reactions may include fever, chills, chest pain, low blood pressure or high blood pressure, shortness of breath, rash and itching.

Inflectra contains a Boxed Warning to alert health care professionals and patients about an increased risk of serious infections leading to hospitalization or death, including tuberculosis, bacterial sepsis, invasive fungal infections (such as histoplasmosis) and others. The Boxed Warning also notes that lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor blockers, including infliximab products such as Inflectra. Other serious side effects may include liver injury, blood problems, lupus-like syndrome, psoriasis, and in rare cases nervous system disorders.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).
[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

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