

## Important Safety Information for Emergency Medicine Physicians About Potential Risks of Infection and Gastrointestinal Perforation With ACTEMRA®

ACTEMRA® (tocilizumab) is an interleukin-6 (IL-6) receptor inhibitor that has been approved by the Food and Drug Administration (FDA) for two indications:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had inadequate response to one or more TNF antagonist therapies with a recommended ACTEMRA® dosing interval of every 4 weeks.
- Children 2 years of age and older with active *Systemic Juvenile Idiopathic Arthritis (SJIA)* with a recommended ACTEMRA® dosing interval of every 2 weeks.

The safety and efficacy of ACTEMRA® for conditions other than RA and SJIA have not yet been established.

**Emergency medicine physicians** should be aware of important safety information regarding ACTEMRA®.

**Serious infections:** Patients treated with ACTEMRA are at increased risk for developing serious infections leading to hospitalization or death. These infections include tuberculosis (TB), bacterial, invasive fungal, viral and other opportunistic infections.

**Gastrointestinal perforations:** Gastrointestinal (GI) perforations have been reported in Phase 3 clinical trials, primarily as complications of diverticulitis. Reported perforations have involved generalized purulent peritonitis, lower GI perforation, fistula and abscess. Most patients who developed GI perforations were taking concomitant nonsteroidal anti-inflammatory medications (NSAIDs), corticosteroids or methotrexate. Patients presenting with new-onset abdominal symptoms should be evaluated promptly for early identification of GI perforation.

In addition to these adverse events, patients treated with ACTEMRA may have elevated hepatic transaminases (ALT, AST) and lipids, and decreased neutrophils and platelet counts. Dosage modifications may be required if laboratory abnormalities occur. Please see the full Prescribing Information for more information.

### **Reporting Adverse Events**

It is important that you report all serious adverse events that occur in patients being treated with ACTEMRA, even if you do not think there is a causal relationship. The information that you provide about these events may inform therapy and monitoring decisions for future patients.

**Reporting is easy and maintains patient confidentiality.** Your patient's name or contact information is not needed. *HIPAA does not apply to this adverse event reporting.* You can report your cases to Genentech or directly to the FDA:

- Genentech at 1-800-ACTEMRA (1-800-228-3672)
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

**Please visit [www.ACTEMRA.com](http://www.ACTEMRA.com) for full Prescribing Information, including Boxed Warning, and Medication Guide.**