

Actemra[®] (tocilizumab) – New indication

- On May 22, 2017, the [FDA announced](#) the approval of [Roche's Actemra \(tocilizumab\)](#) subcutaneous (SC) injection, for the treatment of adult patients with giant cell arteritis (GCA).
- Actemra is also indicated for the following conditions:
 - Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.
 - Treatment of active polyarticular juvenile idiopathic arthritis and active systemic juvenile idiopathic arthritis in patients 2 years of age and older.
- GCA is a form of vasculitis that results in inflammation of the blood vessels. It is a severe autoimmune condition that usually affects those above the age of 50, and is 2 – 3 times more likely to affect women than men. GCA can cause severe headaches, jaw pain and visual symptoms, and if left untreated, can lead to blindness, aortic aneurysm or stroke.
- Actemra is an interleukin-6 receptor antagonist and the first FDA-approved treatment for GCA.
- The new indication for Actemra was approved based on a placebo-controlled study of 251 patients with new-onset or relapsing GCA. Two SC doses of Actemra were compared to two different placebo control groups. The primary efficacy endpoint was the proportion of patients achieving sustained remission from week 12 through week 52.
 - Both Actemra groups (162 mg weekly and 162 mg every 2 weeks, each with 26 weeks of prednisone taper) had a greater number of responders vs. both placebo groups (placebo with 26 weeks of prednisone taper, and placebo with 52 weeks of prednisone taper) (56% and 53.1% vs. 14% and 17.6%, respectively).
- Actemra carries a boxed warning for risk of serious infections.
- The recommended dose of Actemra for adult patients with GCA is 162 mg given once every week as a SC injection in combination with a tapering course of glucocorticoids.
 - Actemra can be used alone following discontinuation of glucocorticoids.
 - IV administration is not approved for GCA.
- Consult Actemra's drug label for dosing recommendations in other indications.