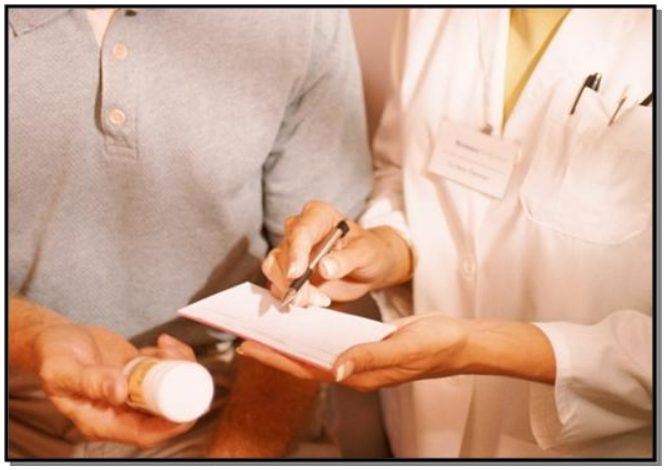
AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH

Specialists in Arthritis Care & Research
2200 Lake Boulevard NE • Atlanta, GA 30319
Phone: (404) 633-3777 • Fax: (404) 633-1870
www.rheumatology.org • info@rheumatology.org



Tocilizumab (Actemra)

Description

Tocilizumab (Actemra) is a new agent in the class of drugs known as biologic disease modifiers. It is used to treat rheumatoid arthritis and the systemic from of juvenile idiopathic arthritis (JIA).. Biologic disease modifiers are genetically engineered drugs that are used to modify imbalances of the immune system in autoimmune disease. Some of these agents block, or modify, the activity of selected cells in the immune system, while others—including tocilizumab—work by blocking certain messenger proteins, known as cytokines, that send signals between those cells. In other words, some medicines directly affect the cells, and others block the communication between cells.

Fast Facts:

- Tocilizumab is a new agent in the class of drugs known as biologic disease modifiers.
- Tocilizumab is administered as a monthly intravenous infusion.
- The risk of infection with tocilizumab appears to be similar to that of other biologic response modifiers.

MEDICATION UPDATE: THE FDA APPROVED TOCILIZUMAB, WITH OR WITHOUT CONCOMITANT METHOTREXATE (MTX) FOR THE TREATMENT OF SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS. THIS FACT SHEET WILL BE UPDATED TO INCLUDE NEW INDICATIONS BY MARCH 2012.

Uses

Tocilizumab has been approved by the Food and Drug Administration (FDA) for use in patients with rheumatoid arthritis who have active disease despite having been treated with one or more of five other biologic modifier drugs that block another cytokine, tumor necrosis factor (TNF), or who have been unable to tolerate such drugs. Tocilizumab has been studied in other patients, such as those who have not responded to methotrexate. Early studies of the use of Tocilizumab in children with systemic JIA showed improvement in fevers, a feeling of well-being, and in blood tests that measure inflammation. The drug is going ongoing study in systemic JIA patients and in children with other forms of JIA. Because the FDA has not specifically approved tocilizumab for use in patients who have only been treated with methotrexate and not an anti-TNF drug, insurance companies may not cover the cost when it is given in this situation.

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How It Works

Tocilizumab works by blocking a cytokine known as interleukin 6, or IL-6, which is believed to be one of the factors that cause inflammation in rheumatoid arthritis. Tocilizumab is an antibody that blocks the spot where IL-6 attaches to the surface of cells. When IL-6 is unable to attach to these cells, it is unable to activate them or turn them on. The result of this is that thecells are unable to drive inflammation in rheumatoid arthritis. The goal of treatment with tocilizumab is to reduce the symptoms of rheumatoid arthritis, including pain and swelling. Studies have also shown that it slows or prevents the joint damage associated with the disease.

Dosing

Tocilizumab is given as an infusion into a vein, either in the hospital or in a doctor's office. The infusions, which take about an hour, are repeated every 4 weeks. Although some patients may improve during the weeks after the first infusion, it may take as long as 6 -12 weeks to see results. For children with systemic JIA, dosing can be as frequent as every two weeks.The tocilizumab dose is adjusted according to the patient's weight. The starting dose is 4 milligrams of tocilizumab per kilogram of body weight, but the dose can be increased to 8 milligrams per kilogram if needed to control arthritis. Tocilizumab may be given by itself or in combination with methotrexate or other non-biologic drugs used to treat rheumatoid arthritis. Tocilizumab should not be given in combination with another biologic agent.

Side Effects

Reactions to tocilizumab infusions, including fever and chills, can occur, but these are rare. Perhaps the most concerning potential side effect with regular therapy is the risk of infection, as it is with most biologic therapies. The primary concern is for common bacterial infections. Unusual infections, such as tuberculosis (TB), have not been seen frequently with tocilizumab, but they do remain a concern, and screening for prior exposure to TB is recommended before starting tocilizumab therapy. Screening and monitoring for TB and other important but unusual infections, including fungal infections, is important during treatment with tocilizumab. Overall, the rate of infection seen in clinical trials with tocilizumab was similar to that seen with other biologic drugs used in the treatment of rheumatoid arthritis.

Tocilizumab has been associated with increased cholesterol levels in some patients. After you start taking tocilizumab, your doctor will periodically do blood tests to check your cholesterol level. If your cholesterol level becomes too high, it is possible you may need to start taking a medication to lower it. Tocilizumab also can cause an increase in some liver enzymes or a decrease in the white blood cells important in fighting infections and/or platelets (important for blood clotting); all of these are measured with regular blood tests. Your doctor will check these tests after you start taking tocilizumab and may need to adjust the dose of tocilizumab or other medications you may be taking, such as methotrexate, if any of these problems occur.

Finally, a rare complication seen with tocilizumab use in clinical trials was bowel perforation, or a hole in the bowel wall. If you have any abdominal pain or bloody bowel movements while taking tocilizumab, you should notify your doctor immediately.

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Points to Remember:

- Tocilizumab is a new biologic response modifier for the treatment of rheumatoid arthritis.
- It has been approved by the FDA for use in patients who have not responded to TNF blockers, and it may be given with or without methotrexate and/or other non-biologic drugs.
- It has been used in children with some forms of arthritis; this is an area of ongoing study.
- It should not be taken with another biologic agent for the treatment of rheumatoid arthritis.
- Blood tests will be used to monitor for increases in cholesterol or liver enzymes and for reductions in blood cell counts while taking tocilizumab.
- Fever or other symptoms of infection and any significant abdominal pain should be reported immediately to your primary doctor and/or your rheumatologist.

For More Information

The American College of Rheumatology has compiled this list to give you a starting point for your own additional research. The ACR does not endorse or maintain these websites, and is not responsible for any information or claims provided on them. It is always best to talk with your rheumatologist for more information and before making any decisions about your care.

ACTEMRA® toclilzumab
www.Actemra.com

ACR Patient Fact Sheet – Juvenile Arthritis
www.rheumatology.org/practice/clinical/patients/diseases_and_conditions/juvenilearthritis.asp

U.S. Food and Drug Administration approves Actemra to treat rare form of juvenile arthritis
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm251572.htm

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Written by Eric Ruderman, MD, and John Tesser, MD, and reviewed by the American College of Rheumatology Communications and Marketing Committee.

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