



MORE COMPLETE CONTROL*

REMICADE, in combination with methotrexate (MTX), is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to MTX

*Compared with MTX alone.

Please see Important Information on page 7.



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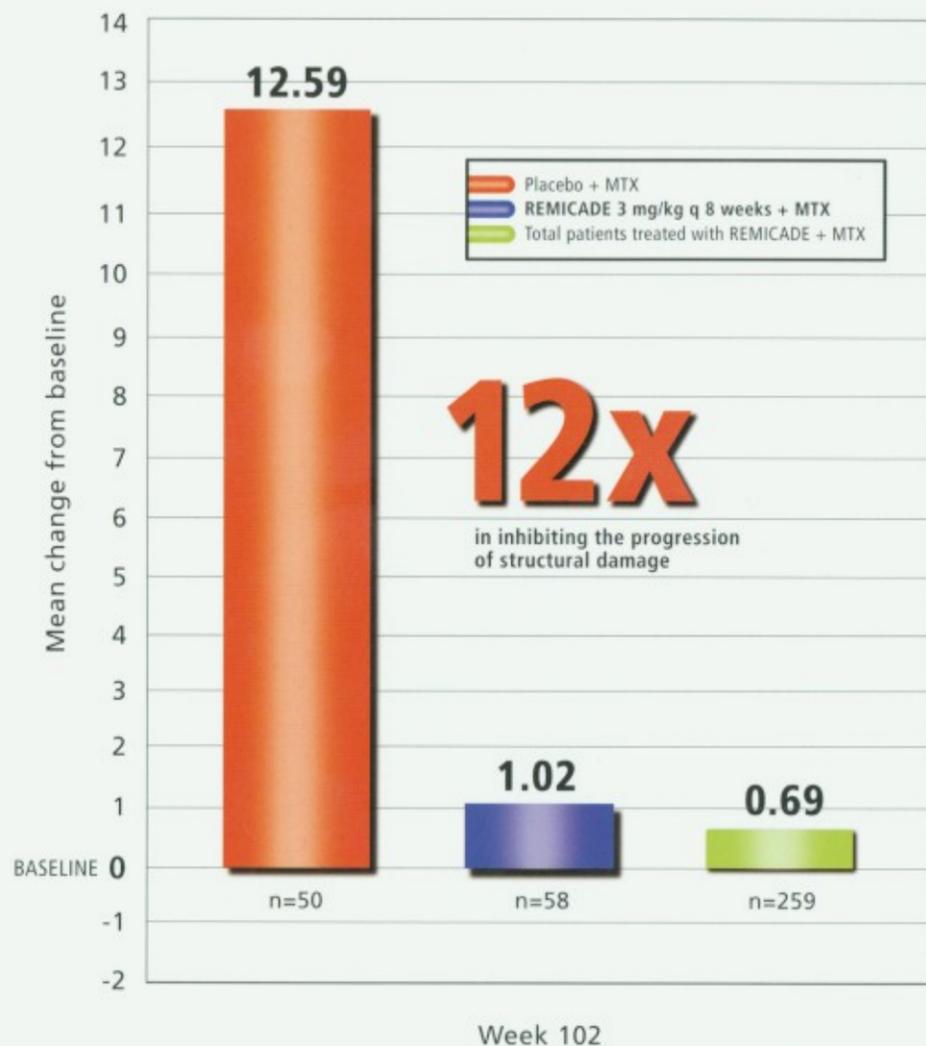
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EFFICACY ACROSS A BROAD RANGE OF PATIENTS

IN PATIENTS WITH ESTABLISHED DISEASE

12 times more effective than MTX alone^{1*}

Mean change in total van der Heijde-modified Sharp score in all patients (median disease duration=8.4 years)^{1*}



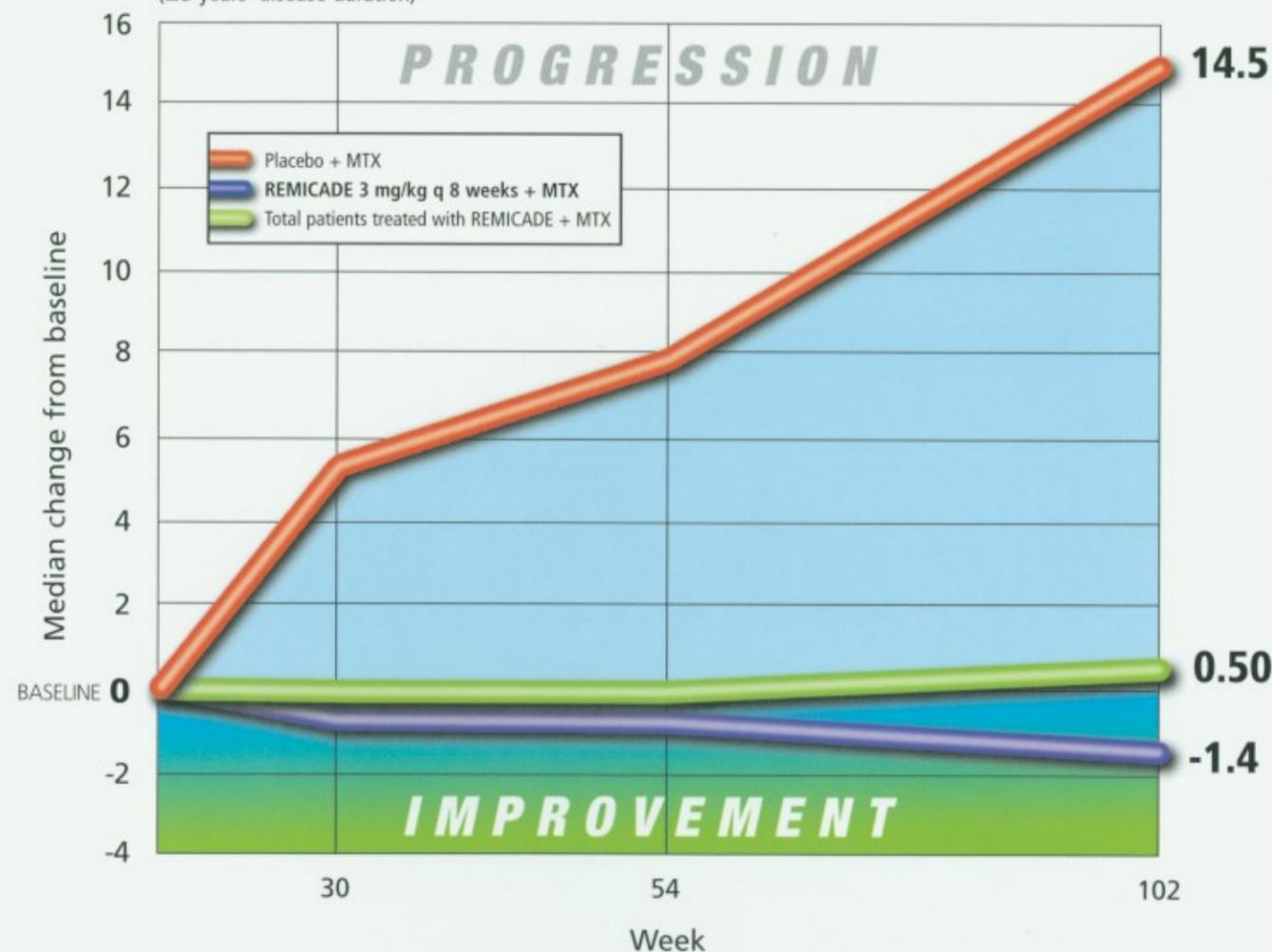
*Results from ATTRACT, a 2-year, multicenter, double-blind, placebo-controlled, randomized, Phase III study of REMICADE with MTX in 428 patients with moderate-to-severe RA. The primary endpoint was the prevention of structural damage as measured by the change from baseline in the van der Heijde modification of the Sharp score. Nearly 50% of patients had advanced disease. All patients were on concomitant stable doses of MTX; there was no MTX washout period. NSAIDs and corticosteroids (≤ 10 mg/day) were permitted at stable doses. No other DMARDs were allowed. There were four REMICADE treatment groups: 3 mg/kg q 8 weeks (n=86), 3 mg/kg q 4 weeks (n=86), 10 mg/kg q 8 weeks (n=87), and 10 mg/kg q 4 weeks (n=81). Eighty-eight patients were randomized to receive MTX plus placebo infusions.

Please see Important Information on page 7.

IN PATIENTS WITH EARLY RA

Based on a subanalysis of patients with ≤ 3 years' disease duration in the ATTRACT trial, which evaluated moderate-to-severe RA patients with an inadequate response to MTX

Median change in total van der Heijde-modified Sharp score in patients with early RA (≤ 3 years' disease duration)¹



Improvement in total van der Heijde-modified Sharp score versus MTX in patients with ≤ 3 years' disease duration^{1*†}

* $P < 0.001$ vs MTX alone.

†Based on a retrospective analysis of patients with ≤ 3 years' disease duration in ATTRACT. Treatment groups at Week 102: placebo plus MTX (n=12), 3 mg/kg REMICADE q 8 wk plus MTX (n=10), and total patients treated with REMICADE plus MTX (n=49).

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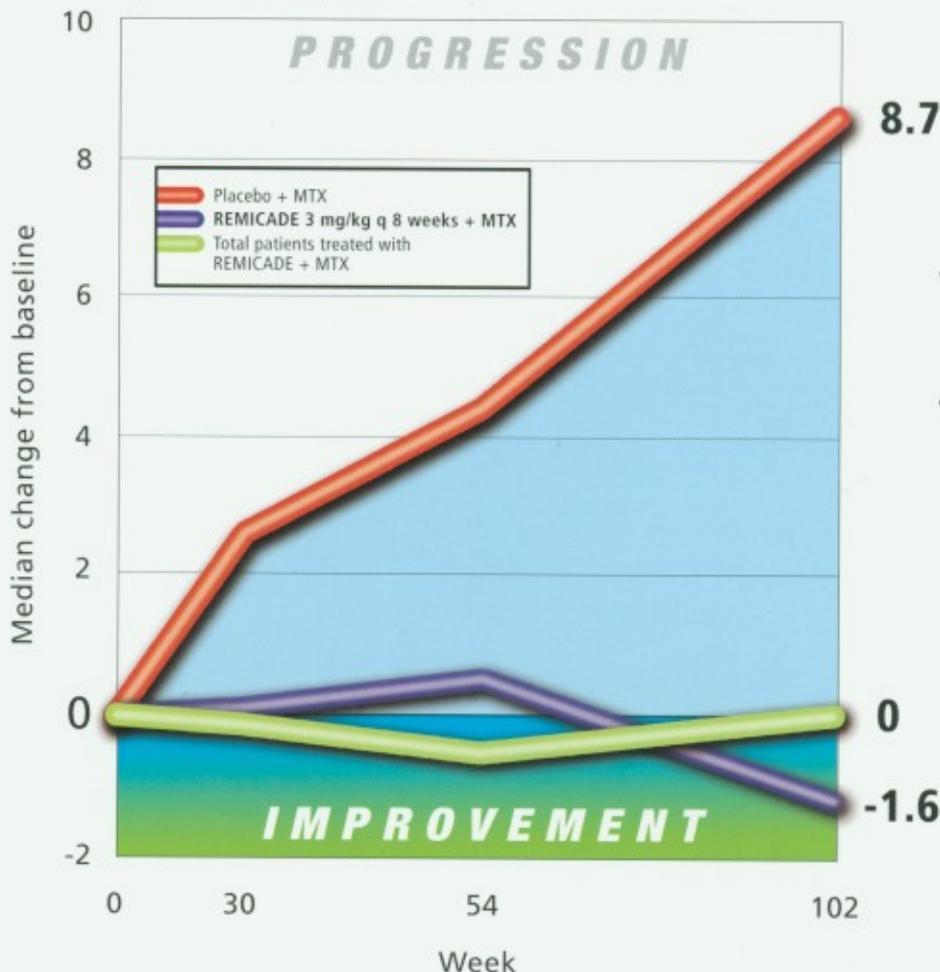
IMPROVEMENT IN BONE EROSION SCORES

In patients with early RA*... REMICADE improved bone erosion scores†

Based on a subanalysis of patients with ≤ 3 years' disease duration in the ATTRACT trial, which evaluated moderate-to-severe RA patients with an inadequate response to MTX

- 1.6-point median reduction in van der Heijde-modified Sharp bone erosion scores over 2 years in patients with ≤ 3 years' disease duration ($P < 0.001$ vs MTX alone)^{1†}

Median change in van der Heijde-modified Sharp bone erosion score in patients with early RA¹



- Based on a retrospective analysis of patients with ≤ 3 years' disease duration in a 2-year, multicenter, double-blind, placebo-controlled, randomized, Phase III study of REMICADE with MTX in 428 patients with moderate-to-severe RA.
- All patients were on concomitant stable doses of MTX; there was no MTX washout period. NSAIDs and corticosteroids (≤ 10 mg/day) were permitted at stable doses. No other DMARDs were allowed. Treatment groups at Week 102: placebo plus MTX (n=12), 3 mg/kg REMICADE q 8 wk plus MTX (n=10), and total patients treated with REMICADE plus MTX (n=49).

* Patients with ≤ 3 years' disease duration.

† Patients who have had an inadequate response to MTX alone.

‡ Patients treated with REMICADE 3 mg/kg q 8 wk.

Please see Important Information on page 7.

THE BENEFITS OF IV ADMINISTRATION

The only anti-TNF- α agent to offer:

- Sustained control with every-8-week maintenance dosing¹
- Patient-tailored dosing to optimize response¹
- In-office administration enabling consistent patient monitoring



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MORE COMPLETE CONTROL



Sustained inhibition of structural damage, regardless of disease duration¹

Improvement in bone erosion scores in patients with early RA¹

Only anti-TNF- α therapy with the benefits of IV administration¹

Experience in more than 500,000 patients worldwide across all indications¹

IMPORTANT INFORMATION:

REMICADE is contraindicated in patients with moderate to severe (NYHA Class III/IV) congestive heart failure (CHF) at doses greater than 5 mg/kg. Higher mortality rates at the 10 mg/kg dose and higher rates of cardiovascular events at the 5 mg/kg dose have been observed in these patients. REMICADE should be used with caution and only after consideration of other treatment options. Patients should be monitored closely. Discontinue REMICADE if new or worsening CHF symptoms appear.

TUBERCULOSIS (TB) (FREQUENTLY DISSEMINATED OR EXTRAPULMONARY AT CLINICAL PRESENTATION), INVASIVE FUNGAL INFECTIONS, AND OTHER OPPORTUNISTIC INFECTIONS, HAVE BEEN OBSERVED IN PATIENTS RECEIVING REMICADE. SOME OF THESE INFECTIONS HAVE BEEN FATAL. PATIENTS SHOULD BE EVALUATED FOR LATENT TB INFECTION WITH A SKIN TEST.² TREATMENT OF LATENT TB INFECTION SHOULD BE INITIATED PRIOR TO THERAPY WITH REMICADE.

Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their disease, could predispose them to infections. Cases of sepsis, histoplasmosis, coccidioidomycosis, listeriosis, and pneumocystosis have been reported. For patients who have resided in regions where histoplasmosis or coccidioidomycosis is endemic, the benefits and risks of REMICADE should be considered before initiation of therapy. REMICADE should not be given to patients with a clinically important, active infection. Use with caution in patients with a history of infection. Monitor patients for infection during or after treatment. Discontinue REMICADE if a patient develops a serious infection.

Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia, some fatal, have been reported. The causal relationship to REMICADE therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias or infection. Consider discontinuation of REMICADE in patients who develop significant hematologic abnormalities.

REMICADE should not be administered to patients with hypersensitivity to murine proteins or other components of the product. REMICADE has been associated with hypersensitivity reactions that differ in their time of onset. Acute urticaria, dyspnea, and hypotension have occurred in association with REMICADE infusions. Serious infusion reactions including anaphylaxis were infrequent. Medications for the treatment of hypersensitivity reactions should be available.

TNF agents, including REMICADE, have been associated with rare cases of new or exacerbated symptoms of demyelinating disorders including multiple sclerosis, and optic neuritis, seizure, and CNS manifestations of systemic vasculitis. Exercise caution when considering REMICADE in all patients with these disorders. Consider discontinuation for significant CNS adverse reactions.



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Please see accompanying full Prescribing Information.

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PI attached.

References: 1. Data on file, Centocor, Inc. 2. American Thoracic Society, Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med.* 2000;161:5221-5247.

**For physician discussion only;
not to be left behind.**

Extensive resources available online at
www.remicade.com



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