



21 June 2004

## FACT SHEET:

### Remicade

#### What is Remicade?

- Remicade is one of a new class of disease modifying anti-rheumatic drugs that target tumour necrosis factor  $\alpha$  (TNF $\alpha$ ) which causes chronic inflammatory disease.<sup>1</sup>
- The active ingredient, infliximab, is a human-mouse protein produced by recombinant technology.<sup>2</sup>
- As an anti-inflammatory agent, Remicade is currently used to treat rheumatoid arthritis, ankylosing spondylitis and Crohn's disease.<sup>2</sup>

#### How does it work?

- When TNF $\alpha$  is over-produced in the joints, it can cause inflammation which can damage the joints. Remicade prevents the harmful effects of TNF $\alpha$  by reducing the inflammation, minimising signs and symptoms and preventing joint damage.<sup>2</sup>
- Remicade reduces the signs and symptoms of inflammation which can cause ankylosing spondylitis or rheumatoid arthritis, improving patients' physical function and reducing the associated pain and discomfort.<sup>2</sup>
- Further studies have shown that Remicade has proven efficacy in the prevention of increased joint destruction, such as erosion and joint space narrowing.<sup>3</sup>

#### Dosage and administration

- Remicade is administered by intravenous infusion over a period of two hours.<sup>2</sup>
- The starting dosage used for treating rheumatoid arthritis is 3mg/kg, with additional doses given at two and six weeks after the initial infusion and then every eight weeks. Methotrexate is given orally to accompany the Remicade infusion.<sup>2</sup>

- For ankylosing spondylitis, the starting dose is 5mg/kg with additional doses given at two and six weeks after the initial infusion and then every six weeks after that.<sup>2</sup>

## Side effects

- Remicade may affect the normal immune system and patients may contract infections more easily. Some cases of tuberculosis have been reported in patients treated with Remicade.<sup>2</sup>
- Infusion and injection site reactions may be observed in patients treated with Remicade, but these are often mild and require minimal treatment.<sup>4</sup>

## INDICATIONS

Remicade is indicated for the treatment of:

### Rheumatoid arthritis in adults

Remicade is indicated for the reduction of signs and symptoms and prevention of structural joint damage (erosions and joint space narrowing) in adult patients with active disease despite treatment with methotrexate. Remicade should be given in combination with methotrexate. Efficacy and safety in rheumatoid arthritis have been demonstrated only in combination with methotrexate.

### Ankylosing spondylitis

Remicade is indicated for the reduction of signs and symptoms and improvement in physical function in patients with active disease.

### Crohn's disease

Treatment of moderate to severe Crohn's disease to reduce the signs and symptoms and to induce and maintain clinical remission in patients who have an inadequate response to conventional therapies.

Treatment of draining enterocutaneous fistulae in patients with Crohn's disease.

## References

1. Schering-Plough Pty Ltd. *GP Information regarding Remicade patients*
2. Remicade<sup>®</sup> Consumer Medicine Information. July 2003
3. Lipsky EP, van der Heijde DFM, St Clair EW, Furst DE, Breedveld FC, Kalden JR, Smolen JS, Weisman M, Emery P, Feldmann M, Harriman GR, Maini RN. (2000). Infliximab and methotrexate in the treatment of rheumatoid arthritis. *NEJM*; **343**: 1549-1602.
4. McColl, G. (2004). Tumour necrosis factor alpha inhibitors for the treatment of adult rheumatoid arthritis. *Experimental and Clinical Pharmacology*. **27**: 43-6