

29 June 2004

Media release

Anti-TNF weapon to combat arthritic conditions

People afflicted with the debilitating disease ankylosing spondylitis now have hope for a pain free life with a ground-breaking treatment for this crippling condition. From 1 August 2004, Remicade (infliximab) will be available in Australia on the Pharmaceutical Benefits Scheme for the treatment of ankylosing spondylitis.*

A chronic inflammatory rheumatic disease, ankylosing spondylitis affects a range of joints, particularly the sacroiliac and lumbar joints at the base of the spine, and also the hip, shoulder, neck and knee joints.^{1,2} Unremitting back pain accompanied by progressive stiffness and lack of mobility are the hallmarks of this disease.

Ankylosing spondylitis can start in patients at any time from age 8 to 45, with the average age of onset being 24 years. Unfortunately, ankylosing spondylitis is not a rare condition, affecting one in 200 adults or 0.5% of the adult population.²

The class of biologic response modifiers,² known as anti-TNF therapies, has revolutionised the treatment of ankylosing spondylitis (AS) and of other chronic rheumatic diseases including rheumatoid arthritis and Crohn's disease.

The most widely used of these anti-TNF agents worldwide, Remicade, works by inhibiting a key causative agent of these inflammatory conditions.

Consultant rheumatologist at Royal Perth Hospital, Dr Andrew Taylor, said Remicade has a dramatic impact on patients' overall wellbeing and quality of life.

"Remicade is the first effective treatment we have been able to offer to severely affected ankylosing spondylitis patients," Dr Taylor said.

* Please refer to HIC website (www.hic.gov.au) for further information

"The activity of their disease is reduced significantly and patients can return to their normal work and recreational pursuits. Physical mobility is increased and there is less need for high dose anti-inflammatory drugs and pain-killers."

“Remicade has proven efficacy in a way that we have never seen before in AS treatments. It is well tolerated and patients can continue taking it for long-term treatment,” he said.

“It is hoped that longer term studies will show that Remicade arrests disease progression preventing ankylosis or fusion of the spine,” Dr Taylor said.

“Remicade alleviates symptoms quickly and many patients report an improvement in their condition within 48 hours of therapy.”

Patrick Baird of Daylesford said treatment with Remicade has changed his life.

Diagnosed with ankylosing spondylitis when he was 19, the 47 year old’s condition has progressively worsened and he has spent the last four years crippled and in constant pain.

“This treatment has given me my life back. It is quite miraculous. The pain and stiffness have gone,” Patrick said.

“Before I started on Remicade I was housebound and often could not get out of bed. I was in constant pain and had no quality of life. I could not work and was taking large doses of pain killers,” he said.

“After the first treatment with Remicade, I started to feel better within 48 hours. It was just unbelievable.”

After 12 months on Remicade, Patrick is now leading a normal life. “I can plan my life again. I am working, can play golf and plan social activities. I feel like I am actively contributing to the lives of those around me again,” he said.

Remicade is the only biologic drug indicated for the treatment of ankylosing spondylitis, rheumatoid arthritis and Crohn’s disease. More than half a million patients have been treated with Remicade worldwide.

Dr Taylor said Remicade’s unique mode of delivery provides an opportunity to ensure patient compliance.

“It is the only anti-TNF therapy administered by infusion and in a supervised medical environment,” he said. “Patients accept the treatment well and in my experience generally prefer to have it given to them in a clinical setting rather than having the responsibility of self-administering their injections,” he said

Patients require only 8-9 doses of Remicade per year for ankylosing spondylitis and slightly less for rheumatoid arthritis.

Notes to editors

Remicade should not be used in patients with severe infections (including tuberculosis), congestive heart failure, hypersensitivity to Remicade, or in patients concurrently being administered anakinra (Kineret) or live vaccines. Remicade is not recommended for use during pregnancy or lactation or in patients with pre-existing or recent onset of central nervous system demyelinating disorders. Adverse events associated with Remicade may include infusion-related reactions, and risk of infections.

PBS Information (Rheumatoid Arthritis): Restricted Benefit. Treatment of adults with severe active rheumatoid arthritis. Refer to PBS or www.hic.gov.au/providers/forms/pbs/mp/infliximab.htm for full restricted benefit information.

PBS Information (Ankylosing Spondylitis): This product is to be listed on the PBS for the treatment of Ankylosing Spondylitis from 1 August 2004. Refer to PBS or www.hic.gov.au

Indications

In Australia, Remicade is approved by the TGA for the treatment of:

- Rheumatoid Arthritis in adults (02/01/02)
- Ankylosing Spondylitis (21/07/03)
- Crohn's Disease (23/06/00)

For more information please refer to the Consumer Medicine Information which accompany this release.

**Dr Andrew Taylor and Mr Patrick Baird are available for interview.
For further information and/or to arrange an interview, please contact:**

Sylvia Bell
Porter Novelli Australia
Tel: 02 9463 7600 or 0438 250 919
Email: sbell@porternovelli.com.au

Anita Fu
Porter Novelli Australia
Tel: 02 9463 7600 or 0401 862 986
Email: afu@porternovelli.com.au

References

1. Arthritis Victoria (2002). Ankylosing Spondylitis, accessed 07/05/04. www.arthritisvic.org.au/Arthritis/ankylosing.pdf
2. Khan, M A. (2002) *Ankylosing Spondylitis. The facts*. Oxford University Press.

REMICADE®

Infliximab(recombinant)

Consumer Medicine Information What is in this leaflet

21 July 2003

This leaflet answers some common questions about Remicade®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Remicade® against the benefits it is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What Remicade® is used for

Remicade® is an anti-inflammatory agent used to treat Crohn's disease, rheumatoid arthritis and ankylosing spondylitis. The active ingredient, infliximab, is a human-mouse protein produced by recombinant technology.

Crohn's disease:

Crohn's disease is a chronic inflammatory disease of the bowel, affecting the distal small intestine and the colon. It may also affect any part of the gut. The cause of Crohn's disease is unknown. The naturally occurring protein, tumour necrosis factor alpha (TNF α), is thought to play an important role in Crohn's disease. When TNF α is over-produced, it can cause inflammation which can induce damage to the bowel wall. Remicade® can prevent the harmful effects of TNF α , thereby reducing the signs and symptoms of Crohn's disease.

Remicade® can also lower the number of abnormal openings through the skin from the bowel (called enterocutaneous fistulae), a common complication of Crohn's disease.

Rheumatoid arthritis:

Rheumatoid arthritis is an inflammatory disease of the joints. The naturally occurring protein, TNF α , is thought to cause rheumatoid arthritis. When TNF α is over-produced in the joints, it can cause inflammation which can induce damage to the joints. Remicade® can prevent the harmful effects of TNF α , thereby reducing signs and symptoms, stopping and preventing joint damage. You will also be given a disease modifying medicine, methotrexate.

Ankylosing Spondylitis

Ankylosing spondylitis is an inflammatory disease of the spine. Remicade® can help to reduce the signs and symptoms of ankylosing spondylitis, thereby improving physical function.

Your doctor, however, may prescribe Remicade® for another purpose.

Ask your doctor if you have any questions about why Remicade® has been prescribed for you.

Before you are given Remicade®

When you must not be given it

Do not use Remicade® if you have an allergy to mouse proteins or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to Remicade® may include skin rash, hives, fatigue, wheezing, difficulty in breathing, and/or low blood pressure.

Do not use Remicade® if you have tuberculosis, infected abscesses, another infection, a chronic infection or a history of recurrent infection.

Do not use Remicade® if you are already taking another medicine which contains an active ingredient called anakinra.

If you have never been given Remicade® and have congestive heart failure, you should not use it.

Before you are given it

You must tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Like most medicines, Remicade® is not recommended in pregnancy and breast-feeding.

You must use adequate contraception to avoid falling pregnant for at least 6 months after the last treatment with Remicade®.

If you are breastfeeding, your doctor will advise you to discontinue breastfeeding for at least 6 months after treatment with Remicade®.

Remicade® may affect the normal immune response. You might get infections more easily. Some cases of tuberculosis have been reported in patients treated with Remicade®.

Before starting Remicade®, it is important to tell your doctor if

you have ever had or been in close contact with tuberculosis.

If symptoms of tuberculosis (persistent cough, weight loss, listlessness, fever), or any other infection appear during therapy notify your doctor immediately.

If you have a long history of Crohn's disease and have been taking medicine that reduces the activity of the body's natural defences, you are more likely to develop infections and lymphomas.

If you suffer from congestive heart failure, ensure that your doctor is aware of your condition as steps must be taken to monitor any changes to your condition during treatment with Remicade®.

Your doctor will discuss with you the benefits of using Remicade® against the potential risks.

Taking or being given other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when being given Remicade® with other medicines.

How Remicade® is given

Remicade® is only available on prescription. Remicade® is given by your doctor in a drip into a vein (called an infusion) over at least 2 hours. A period of observation follows treatment.

Crohn's disease:

The recommended treatment for Crohn's disease is an initial infusion of 5 mg/kg followed by additional doses of 5 mg/kg at 2 and 6 weeks after your first infusion and

then every 8 weeks after that. In some cases your doctor may decide to increase your dose up to 10 mg/kg.

The recommended dose for closure of fistulae is also 5mg/kg. You may be given two additional infusions at 2 and 6 weeks after the first infusion.

Rheumatoid arthritis:

The recommended starting dose for rheumatoid arthritis is an infusion of 3 mg/kg. You will get additional doses at 2 and 6 weeks after your first infusion and then every 8 weeks after that. You will also be taking methotrexate as part of your treatment.

Ankylosing Spondylitis:

The recommended treatment is an infusion of 5 mg/kg. You will get additional doses at 2 and 6 weeks after your first infusion and then every 6 weeks after that.

While you are given Remicade®

Things you must do

If the medicine starts to upset you or your symptoms become worse, tell your doctor, nurse or pharmacist.

You should take adequate contraceptive measures to avoid pregnancy during treatment and for at least 6 months after the last infusion of Remicade®.

Things to be careful of

Remicade® may affect the normal immune response. There is a possibility that you may be more prone to infections. Tell your doctor if you think you have an infection. You will be watched closely.

Tell your doctor immediately if you develop a skin rash or hives.

Your doctor may discontinue Remicade® until the symptoms go away and then begin giving the medicine again. Symptoms will resolve with appropriate treatment.

Remicade® is unlikely to make you drowsy. If you are tired, do not drive a car or work with machinery.

If you suffer from congestive heart failure, tell your doctor immediately if your condition worsens.

Side effects

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given Remicade®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

During the infusion of Remicade® the following reactions may occur:

- fever or chills
- itchiness or hives
- chest pain
- low blood pressure
- high blood pressure
- shortness of breath

These reactions are more likely to occur during the first and second infusion. Side effects may appear up to six months after the last infusion.

Tell your doctor immediately if you notice any of the following:

- pain or tenderness in chest, muscles, joints or jaw

- swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- fever
- rash
- itching
- symptoms that may indicate heart failure, e.g. shortness of breath, especially with exercise or lying down, or swelling of your feet.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- headache
- nausea
- itching
- dizziness and light-headedness
- fatigue
- fever
- rash
- hives
- sore throat
- coughing
- hoarseness
- shortness of breath
- chest pain
- diarrhoea
- muscle pain
- abdominal pain
- vomiting
- indigestion
- weight loss, muscle wasting
- problems with urination
- changes in the way your heart beats, for example, if you notice it beating faster
- flushing
- skin redness
- dry skin or increased sweating
- your rheumatoid arthritis becomes worse

Most of the side effects are mild to moderate in severity. Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After Remicade[®] has been stopped

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Remicade[®].

- skin rash or hives
- frequent infections

Tell your doctor if you notice any other effects.

Storage

Remicade[®] should be stored at 2°C to 8°C. (Refrigerate. Do not freeze.) Do not use beyond the expiration date.

Product description

What it looks like

Remicade[®] comes as a white powder in a glass vial.

Ingredients

Active ingredient:

Infliximab (recombinant) 100 mg per vial

Inactive ingredients:

- sodium phosphate monobasic monohydrate
- sodium phosphate dibasic dihydrate
- sucrose
- polysorbate 80

Supplier

In Australia:

Schering-Plough Pty Limited
11 Gibbon Road
Baulkham Hills NSW 2153
AUSTRALIA

Australian Registration Number

AUST R 73827

Date of Preparation

21 July 2003