BETAFERON® is a Prescription Medicine. Use strictly as directed. Consult your pharmacist or other health professional in case of side effects. BETAFERON® is reimbursed for some patients. See your neurologist or specialist for details.

**Abridged Patient Information.**

BETAFERON® (interferon beta-1b). Each mL of prepared solution contains 0.25mg or 8 million IU of Interferon beta-1b. BETAFERON® is for use in patients who have early stage, relapsing remitting or secondary progressive multiple sclerosis. BETAFERON® must not be used if you are allergic to beta interferon -1b, human albumin or manitol. BETAFERON® should not be used if you are pregnant or trying to become pregnant, are breast feeding, suffer from severe depression, have liver failure or uncontrolled epilepsy.

BETAFERON® should be used with caution if you have heart problems, blood or bone marrow disorders, pancreatitis, kidney disease or severe injection site reactions. BETAFERON® may affect liver function and rare cases of liver damage and skin breakdown (causing scar formation) have been reported. The most common side effect is to experience ‘flu-like’ symptoms such as fever, chills, headache and painful joints. These events tend to decrease with time. To minimise the risk of injection site reactions the correct sterile injection technique should be followed and appropriate training is required.

For further information please consult the Consumer Medicine Information available on www.medsafe.govt.nz or phone 0800 233 988 or contact Bayer New Zealand Limited, PO Box 2825 Auckland 1140.
Current MS therapy has changed the lives of thousands of people living with MS for the better. While corticosteroids are used to treat acute symptoms, the newer immunomodulating agents such as beta interferons can delay the natural course of the disease. This brochure explains the mechanism of action and protective effects of Betaferon® on the nerve cells.

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Corticosteroids during acute attacks

Corticosteroids are the standard medications prescribed during acute relapses to reduce duration and intensity of these attacks. Corticosteroids (other common names are glucocorticosteroids or simply steroids) derive from cortisone, a hormone naturally produced in our body. Administered corticosteroids are slightly different from the body’s own cortisone, but they have the same effect and can be given by infusions over a few days.

Cortisone has many positive effects in the treatment of an attack, but the most useful effect is its suppression of the immune system by reducing the migration of immune cells into the brain (anti-inflammatory effect). Inflammation and water retention (oedema) in the Central Nervous System (CNS) are reduced and the function of the blood-brain-barrier is restored.

Acute short-term treatment is generally well tolerated. However, corticosteroids are not recommended for long-term treatment. They only assist in recovery from an acute relapse. Long-term use of corticosteroids can induce side effects like osteoporosis.

For more detailed information please ask your doctor.

Current MS therapy

Even though there is no cure, MS can be dealt with in different ways.

MS is treated according to your individual situation:

- **Acute relapses are treated with corticosteroids.**

- **Immunomodulating agents are used to delay the natural course of the condition by modifying the immune response, thus causing less inflammatory activity in the brain.** Immunomodulating agents can have an impact on the long term course of your MS.
Immunomodulating therapies

What is meant by an immunomodulating therapy? Some medications can modify specific actions of certain cells within the body’s defence system (immune system), therefore “resetting” it when it is altered by a condition such as MS. These medications, also referred to as immunomodulating agents, act in various ways to the benefit of the patient (please see table on page 8/9 for an overview). One of the most widely prescribed immunomodulating therapies in MS are the beta interferons.

With the introduction of immunomodulatory drugs, MS therapy underwent a revolution in terms of being able to reduce relapse rates and the progression of MS.

Reducing relapses or lengthening the time spans between them has important neurological benefits, such as

- less minor symptoms
- less severe symptoms
- less hospitalisations due to MS
- less residual deficits
- less disruption of life

and thus a significant positive impact on overall health and well-being.

Beta interferon

Composition of beta-interferons

Interferons comprise a family of proteins which are naturally produced by certain immune cells to fight infections and modulate the immune system. They act as anti-inflammatory agents and against viral infections. Modern biotechnology makes it possible to synthesise and produce these natural proteins and to use them as ‘drugs’. Interferons are classified as alpha, beta and gamma, depending on their molecular structure. They all play a role in the natural defense mechanism of the immune system.

Interferon beta-1b (Betaferon®) is a modified, but natural protein produced by bacteria (Escherichia coli) that has been used successfully for many years in MS therapy (Figure 1).
# How can I benefit from an immunomodulating therapy in MS?

<table>
<thead>
<tr>
<th>Product</th>
<th>Interferon beta-1b</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand name</strong></td>
<td>Betaferon®</td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Bayer Schering Pharma - Bayer Australia Limited</td>
</tr>
<tr>
<td><strong>What kind of MS can be treated?</strong></td>
<td><strong>How can I benefit from this?</strong></td>
</tr>
<tr>
<td>Clinically Isolated Syndrome (CIS): refers to a single subacute clinical event and at least two MRI lesions suggestive of MS. Relapsing-remitting MS: characterised by acute attacks (relapses) followed by complete or partial remissions and is the most common type of MS at disease onset. Secondary progressive MS with evidence of disease activity: characterised by a steady accrual of fixed disability after an initial relapsing remitting course.</td>
<td>Since Betaferon® is indicated for clinically isolated, relapsing-remitting and secondary progressive forms of MS, almost everyone living with the condition can potentially be offered the medication. Betaferon is not indicated for patients with primary progressive MS.</td>
</tr>
<tr>
<td><strong>Dosage, Frequency</strong></td>
<td>250 µg or 8 million IU every other day</td>
</tr>
<tr>
<td><strong>Injection method</strong></td>
<td>Under the skin</td>
</tr>
<tr>
<td><strong>Supplied as</strong></td>
<td>Vials and prefilled diluent syringes</td>
</tr>
<tr>
<td><strong>Autoinjectors</strong></td>
<td>Betaject® Comfort</td>
</tr>
<tr>
<td><strong>Storage requirements</strong></td>
<td>Store at room temperature (max 25°C) for up to 2 years (see expiry date on the vial)</td>
</tr>
</tbody>
</table>

An effective dose and proven treatment regimen. An easy way of self-injecting the medication, similar to millions of patients with diabetes. Injection solution is always freshly prepared. Hence no preservatives are added to the medication. A state-of-the-art injection device will not only help to satisfy your particular needs but will also help to overcome needle phobia and reduce the occurrence of injection site reactions. The flexibility in storing Betaferon® allows for increased convenience on a day-by-day basis.
Figure 2: Possible mechanisms of action of interferon beta-1b

No interferon beta treatment

Interferon beta treatment

**Mechanism of action of beta interferon**

As you may remember from the first brochure of this series, the body’s immune system may falsely target its own tissue and thus start to attack it (autoimmune disease). Beta interferon treatment decreases the permeability of the blood-brain-barrier (BBB). If immune cells are stopped from crossing the BBB, much of the source of inflammation in the brain is stopped. Therefore, the migration of activated immune cells into the brain is successfully inhibited.

Beta interferon has both antiviral and immunoregulatory properties. These can reduce inflammatory actions and help control abnormal immune responses as seen in MS (Figure 2).

* Illustration not to scale.
**Protection of myelin and axons**

By inhibiting destructive macrophages, beta interferon protects the myelin layers and axons from further destruction.

*Figure 3: IFN beta reduces the number of activated macrophages*

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Loss of nerve fibres occurs during the early stages of MS and destruction is not restricted to visible lesions seen in MRI scans, but is also present in otherwise healthy appearing “white matter” of the central nervous system.

Our brain is capable of compensating for early nerve damage by relocating function and remyelinating nerve tissue fibres, but if continuous inflammation destroys myelin and axons beyond a certain threshold, compensatory mechanisms fail and irreversible damage occurs. This is why treatments which reduce inflammation may prevent or delay irreversible damage thus delaying progression of permanent neurological deficits.

*Treating MS early with a beta interferon such as Betaferon® has been shown to slow the accumulation of nerve injury. However, MS is a variable condition and your doctor will decide on the suitability of treatment for your type of MS.*

**Manageable side effects**

Common side effects of beta interferons are flu-like symptoms after administration and sometimes injection site reactions that can be managed by suitable treatment. Please refer to the product leaflet for more detail on side effects.
**Glossary**

**Autoimmune diseases:** Diseases in which the body's immune system may falsely recognise own tissue as foreign and therefore start to attack it. These include diabetes, rheumatoid arthritis and MS.

**Axons:** The ‘cables’ of the nerve cells that transmit impulses from the brain to different areas of the body and inform the brain about sensory perceptions. Each nerve cell has just one axon. An axon is a single fibre that sends nerve impulses away to other nerve cells. Axons are normally protected by layers of myelin, which can be destroyed in MS, leading to the symptoms associated with MS.

**Blood-brain-barrier:** A natural barrier separating brain tissue and blood vessels. In active MS, the blood-brain-barrier is damaged, so that inflammatory cells, transported in the blood, may enter the brain.

**Corticosteroids:** Drugs derived from cortisone. They are also referred to as glucocorticosteroids or steroids and inhibit inflammation.

**Immunomodulating drugs:** e.g. beta interferons, administered as first-line therapy in MS to delay the natural course of the disease by shifting the immune system to a less aggressive status and causing less inflammation activity in the brain.

**Lesions:** Certain areas in the brain where demyelination has taken place.

**Macrophages:** Cells that may be motile. They have the ability to incorporate and digest foreign particles but if misdirected also own tissue. In MS, they attack and destroy the myelin layers surrounding nerve cells.

**Myelin:** Consists of lipids and proteins. It is a fatty insulating layer surrounding the nerve fibres of the central nervous system. Myelin is required to speed up transmission of electrical signals going back and forth to the brain and spreading throughout the entire body.

**Relapse:** Another term for an attack or episode that followed an earlier one. In MS, demyelination of nerve fibres leads to impaired transmission of electrical impulses and loss of function, finally resulting in relapses.

**Remission:** Refers to an improvement of symptoms. It can be complete or incomplete. The opposite of remission is exacerbation.