

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

Abridged Patient Information.

BETA FERON® (interferon beta-1b). Each mL of prepared solution contains 0.25mg or 8 million IU of Interferon beta-1b.

BETA FERON® is for use in patients who have early stage, relapsing remitting or secondary progressive multiple sclerosis. BETA FERON® must not be used if you are allergic to beta interferon -1b, human albumin or manitol. BETA FERON® 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.

BETA FERON® should be used with caution if you have heart problems, blood or bone marrow disorders, pancreatitis, kidney disease or severe injection site reactions. BETA FERON® 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.

Betaferon® - The benefits of modern MS therapy



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In this brochure you will find **information about Betaferon®**, a treatment that can modify the course of your MS. You will learn what MS does to your nervous system. You will be introduced to what is called the **“iceberg phenomenon”**, i.e. the non-visible nerve injury in MS and find answers to questions you may have regarding what **effects and benefits you can expect from treatment with Betaferon®**.

Another topic discussed in this brochure is the **importance of dose and how often the dose should be administered**. As with all medications it is not only the size of the dose that is important but also the frequency of administration, ensuring that consistent drug levels are maintained at all times.

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A treatment that can modify the course of MS

MS is a condition that has a very variable course in each patient. This means that it is not possible to predict with certainty how your individual course might turn out. While many people with MS may be left relatively unaffected by MS for many years, others will experience early neurological deficits which affect their lives.

Up until 2000, there was no approved treatment available for MS. Neurologists experimented with many drugs but without any convincing outcomes. Interferon beta treatment for the first time clearly demonstrated effects on relapses and inflammation as shown by magnetic resonance imaging (MRI) of the brain. Though not a cure, beta interferons greatly improved the management of MS, since there is also evidence that the acute symptoms maybe lessened and the progression of MS delayed with their use.

In order to understand how beta interferon treatment can benefit MS, it is useful first to find out a little more about MS by reading other brochures in this series.

Non-visible early nerve injury in MS

MS is a condition that damages the nerves in the central nervous system (CNS). Damage to nerve pathways can lead to a loss of the function controlled by those nerves. However, our brain is capable of compensating for early nerve injury by switching to alternative nerve paths that can assume the same function.

For example, you might imagine that, if the quickest road from your house to your nearest shopping centre were blocked you would find another route. If this also became blocked you would again find another way and so on ...

By using alternate pathways for as long as possible, the brain can compensate for early nerve injury. Thus, in early stages of MS, symptoms may still be absent, even though there is underlying MS activity. However, eventually the loss of nerves will exceed a compensation threshold, and signs of MS may become visible.

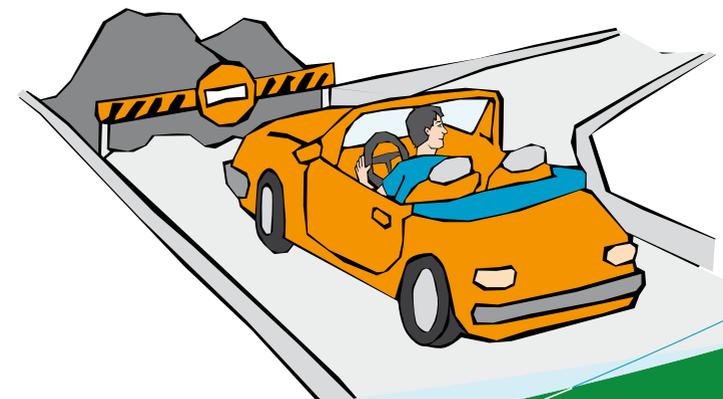


Figure 1:
What do you do if your way is blocked? You find another route. This is what our brain also tries to do even if some nerves are damaged

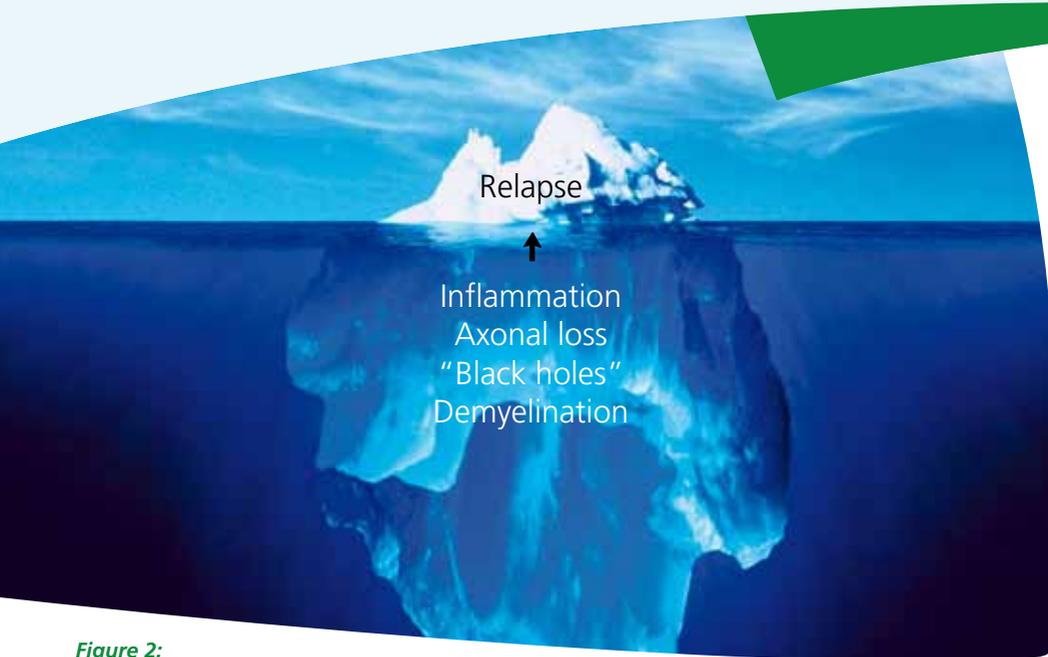


Figure 2:
Most activity takes place unseen beneath the surface – somewhat like an iceberg

Visible clinical MS symptoms are “the tip of an iceberg”

MS may be compared to an iceberg, where most MS activity takes place unseen “beneath the surface” and only a fraction is visible as symptoms “above the surface”.

By means of MRI imaging it has been determined that there is ongoing inflammation of nerves within the brain which is left unnoticed by patients and neurologists.

Relapses are only the tip of the iceberg and more pronounced symptoms may occur over time as axonal loss continues. Therefore it is important to reduce the onset of symptoms and delay the progression of MS with an appropriate treatment.

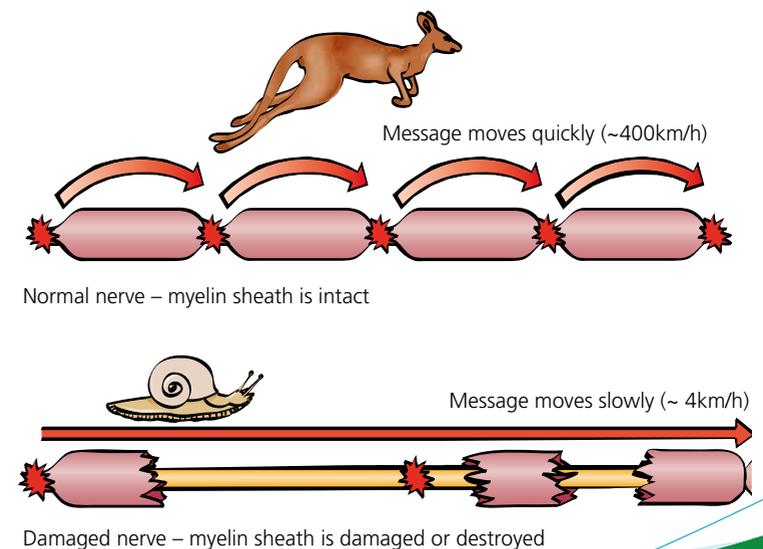
Irreversible nerve injury in MS – what is lost cannot be regained

MS activity may lead to injury to the insulating sheath around the nerve axons. While damage to the myelin may at least be partially repaired, any damage to the nerve axons is permanent. If the brain cannot compensate for these damaged nerve pathways then the function once controlled by the effected nerves may be lost forever.

Treating MS early on can help to:

- delay the onset of the next relapse or set of symptoms
- reduce the overall level of MS activity in the brain
- prevent future permanent injury to the nerve axons

Figure 3:
Inflammation and nerve injury (axonal loss) in MS



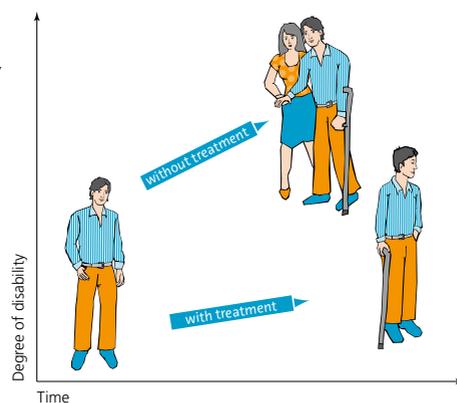
Treatment with Betaferon® (interferon beta-1b)

The course of MS differs from person to person and may even change over time. You and your doctor have recently decided to start therapy with Betaferon® because you have reached a point in time, where starting treatment is best for you.

More and more experts are convinced, that newly diagnosed people with MS should start MS treatment as early as possible to limit MS related nerve injury and postpone future potential disability progression.

In this respect starting treatment early with Betaferon® is like taking out an insurance policy. The first signs of MS can be mild and quickly followed by a full recovery but there is no certainty that events in years to come will be benign. Betaferon® provides reassurance that you are doing the best you can for your future and the best effect comes with early treatment.

Figure 4:
MS treatment has the potential to slow down the progression of MS



Clinical data shows that treating MS early with Betaferon® reduces the rate of progression of disability.

Betaferon® is approved for use in people with as early as Clinically Isolated Syndrome (CIS) suggestive of MS, as well as relapsing-remitting and secondary progressive MS. It is a medication with the following characteristics:

Injection method

injection just under the skin, similar to an insulin injection for diabetes.

Injection frequency

every other day to ensure a steady level of the active drug.

Product presentation

the drug is freshly prepared just before injection, thereby reducing the need for any preservatives and making for a more comfortable injection.

Storage

The medication can be stored at room temperature allowing for flexibility in daily activities and when travelling.

Treatment effects and benefits of Betaferon®

Betaferon® was one of the first MS therapies to be introduced that could modify and re-balance specific actions of the immune system and therefore alter the course of MS.

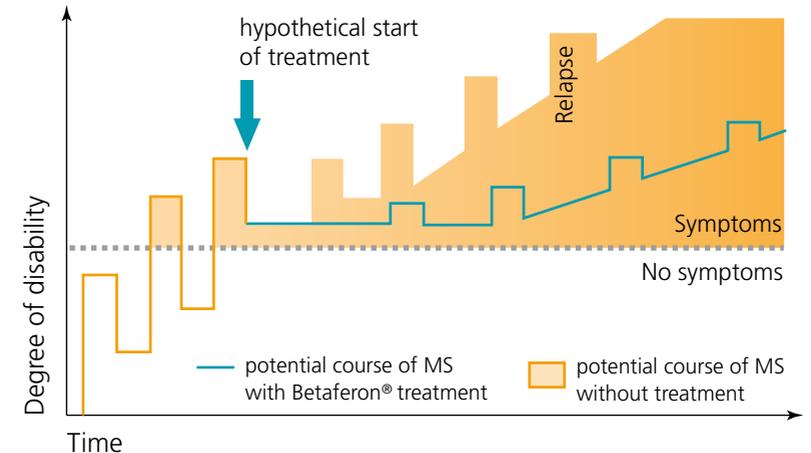
While MS-modulating medication, such as Betaferon®, cannot reverse the accumulated signs and symptoms of the condition, they may help to alter the future course for the better.

As you can see in figure 5, these medications do not completely eliminate all future MS activity. Therefore, even with the help of these drugs, future MS symptoms may still be experienced, although to a lesser degree.

Overall, Betaferon® has the potential to:

- Slow down the progression of MS
- Reduce the severity and frequency of relapses and increase relapse-free time
- Reduce the number of days spent in hospital due to MS
- Reduce the amount of corticosteroids needed for acute treatment
- Reduce MS activity as shown by MRI (magnetic resonance imaging) images of the brain

Figure 5:
The benefit of Betaferon® treatment: Severity and frequency of relapses is reduced and relapse-free time is prolonged



Scientific studies have also shown that people on Betaferon® spent more time in better shape and had a better quality of life when compared to those that were not on treatment.

There is also evidence emerging that some of the available immunomodulating treatments, such as Betaferon®, may offer some protection against future and more permanent damage to the nerve axons. This is in addition to preventing the inflammatory activity that causes the usually reversible symptoms of MS.

Figure 6:
Just as a helmet can protect a cyclist's head from injury, immunomodulating treatment with Betaferon® may help to protect your brain from MS injury to the nerve axons



The importance of efficacy

When deciding on a treatment for you, your doctor has chosen a treatment that he considers highly effective for your type of MS. Choosing an effective and suitable therapy for your MS is a very important consideration. This is particularly important when we consider that MS injury to nerves is permanent and any function that is lost may not be fully regained.

Comprehensive rehabilitation measures may help to minimise the consequences of the condition. Therefore your doctor will want to ensure that you receive a highly effective treatment.

The importance of good tolerability

Betaferon® has been in widespread use for over a decade, is derived from a naturally occurring protein in the body and has a very favourable record for being well tolerated. Attention to the practical aspects such as comfortable and convenient injection systems, has strengthened its tolerability profile.

Dosing and frequency of injecting

The researchers that devised the injection pattern for Betaferon® found that amongst other factors, the dose and frequency of injection could contribute significantly to the overall effectiveness of the treatment...

In devising an effective dosing regimen, the Betaferon® researchers found that injecting once every second day is necessary to keep the levels of the active drug in the blood consistently high in order to maintain a strong beneficial effect.

Betaferon® has a quick onset of action.

MS studies to date have shown that the effect of Betaferon® treatment can be seen soon after drug therapy has started. In particular, a clear effect on MS inflammation (as measured by MRI images of the brain) has been demonstrated. This effect can be visible only a few weeks after starting therapy.

A reduction in relapses can be visible only two months after commencement on Betaferon® treatment as compared to patients treated with a placebo treatment.

When considering the likely damage caused by early irreversible MS activity in your body, it is important that the benefit from your chosen treatment occurs as quickly as possible and is not delayed.

Figure 7:
Time counts



Antibodies to beta interferons

Antibodies are natural substances produced in the body in response to foreign invaders, particles or proteins. Among other things, these antibodies help the immune system to recognise and quickly defend the body against viral and bacterial infections.

As you might expect, the body also recognises some drugs, such as MS medications, as “foreign” and can sometimes develop antibodies against the drugs. At high levels these antibodies may reduce the effectiveness of the treatment. This is called neutralising activity and occurs in some patients. There is much debate amongst MS experts about the role these antibodies play in MS treatment. Some people with MS develop them, whereas others do not. And even if they do develop, they tend to disappear over time.

What is known is that many people with MS continue to do well even if they develop these antibodies to treatment.

For you and your doctor it is important to monitor the treatment effects based on clinical signs, symptoms and MRI parameters.

The right treatment for you

Although beta interferon treatment is not a cure, it can help to reduce MS activity with beneficial effects by slowing the progression of the disease and reducing the frequency and severity of MS related relapses.

In this brochure you will have learned the importance of reducing MS activity and thereby reducing or delaying the occurrence of MS symptoms in the future. An understanding of this will help you realise how important it is that you receive an effective treatment for your MS.

Glossary

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.

Beta interferons are naturally occurring proteins. They can modify specific actions of the body's immune system and are therefore used to treat autoimmune diseases like MS.

Immunomodulating medications such as beta interferons are administered as basic therapy in MS to delay the natural course of the disease by shifting the immune system to a less aggressive status and thus causing less inflammation activity in the brain.

Lesions: Refer to certain areas in the brain or spinal cord where demyelination has taken place.

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 relapse.

Notes

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