Parker & Waichman, LLP Attorneys at Law
Betaseron Information Guide

Manufacturer:
Chiron Corp.

Generic Name:
Interferon beta-1b

Date Approved:
July 23, 1993

Status:
On the market

Approved Uses:
Multiple Sclerosis

Serious Side Effects:
Hepatic injury
Autoimmune Hepatitis
Severe liver damage
Skin damage

Related Topics:
Defective Drugs

The Case Against Betaseron:

The FDA approved Betaseron on July 23, 1993. Sclerosis. Betaseron is approved for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations.

On April 22, 2005 healthcare professionals were warned regarding the prescribing information for Betaseron (interferon beta-1b) as it pertains to hepatic toxicity.

There have been reports during post-marketing safety surveillance of serious hepatic injury including autoimmune hepatitis and severe liver damage leading to hepatic failure and transplant. Liver function testing is recommended at regular intervals (one, three, and six months) following introduction to Betaseron therapy, and then periodically thereafter in the absence of clinical symptoms.

Flu-like symptoms are a common side effect associated within the initial weeks of taking Betaseron. Injection site necrosis [skin damage], which occurs in about 5% of patients during the first four months of therapy, has been reported in post-marketing studies even after a year of treatment.

During the clinical trial of interferon beta-1b, there were four suicide attempts and one completed suicide among those taking interferon beta-1b. Common side effects include flu-like symptoms (fatigue, chills, fever, muscle aches, and sweating) and injection site reactions (swelling, redness, discoloration, and pain).

If you or a loved one has been injured by Betaseron, Parker & Waichman, LLP will evaluate your case for free. Click here for a free, no obligation, case evaluation.

Betaseron (Interferon beta-1b)
From Wikipedia, the free encyclopedia.

Interferon beta-1a is a drug in the interferon family used to treat multiple sclerosis. It is produced by mamalian cells while Interferon beta-1b is produced in modified E. coli bacteria. It is the pioneering treatment for multiple sclerosis with, as of 2005, 16 years of data demonstrating its safety and efficacy. Interferons have been shown to have about a 30-35% reduction in the rate of MS relapses, and to slow the progression of disability in MS patients. None of the products on the market is a cure, but patients today who start early on Inteferons can curb the disease enough that they are much less likely today to end up in a wheelchair than they were 10 years ago, before these treatments were known.

It is believed that Interferon-Beta based drugs achieve their beneficial effect on MS progress via their anti-inflammatory properties. Studies have also determined that Interferon-Beta improves the integrity of the blood-brain barrier (BBB)-- which generally breaks down in MS patients, allowing increasing amounts of undesirable substances to reach the brain. This strengthening of the BBB may be a contributing factor to Interferon-Beta's beneficial effects. These studies were carried out in vitro (outside a living organism - a "petri dish" experiment), so it does not necessarily mean it works the same in people.

Nonetheless, Interferons have side effects. The two main ones are flu-like symptoms, and injection-site reactions. The flu-like symptoms tend to happen immediately after the injection, and last for about half a day. In many patients, these symptoms diminish over time, but some patients continue to experience them over the long term. One can mitigate these symptoms by using a dose that's injected less frequently, and by taking the medication before bedtime. The injection-site reactions can be mitigated by rotating injection sites, or also by using one of the medications that is injected less frequently. These side effects are onerous enough that many patients take Interferons (or Copaxone, the other disease-modifying therapy that is available) for six months or a couple years and then decide to drop off treatment.

Most commonly reported side effects are injection site disorders, flu-like symptoms, elevation of liver enzymes and blood cell abnormalities. Patients with depression, seizure disorders, or liver problems, should discuss treatment with Rebif with their doctors.

While these drugs improve certain diagnostic test results, many patients report no perceived improvement, along with serious side-effects that substantially reduce quality of life. It is important to recognize that these drugs are intended to treat symptoms but do not cure multiple sclerosis, and it is debatable whether they provide meaningful benefit in the short or long term. Furthermore, tolerance develops over time in some patients, due to the development of "neutralizing antibodies," which reduce the effectiveness of these drugs while side effects may persist even after discontinuation.