



## New AVONEX® Dosing Innovations for People with Multiple Sclerosis Now Available in US

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*- AVONEX PEN® Offers Multiple Sclerosis Patients Taking AVONEX Enhanced Administration and Dose Titration with AVOSTARTGRIP™ Allows More Tolerable Initiation -*

WESTON, Mass.--(BUSINESS WIRE)--[Biogen Idec](#) (NASDAQ: BII) announced that two new dosing innovations designed to help patients receiving once-a-week AVONEX (interferon beta-1a) for relapsing forms of multiple sclerosis (MS) are now available in U.S. pharmacies:

- The new AVONEX PEN (AVONEX 30mcg/0.5mL solution for injection) is the first intramuscular (IM) autoinjector for chronic use, designed to enhance the self-injection process for patients receiving AVONEX therapy.
- A new dose titration regimen, facilitated by the AVOSTARTGRIP titration devices, provides patients with the option to gradually increase the dose of AVONEX at treatment initiation to reduce the incidence and severity of flu-like symptoms that patients may experience with therapy.

These product enhancements offer the potential for a more tolerable initiation and an easier injection process compared to the AVONEX Prefilled Syringe.

"It is our priority to continue to improve our existing treatments like AVONEX, which patients have relied on to effectively treat their MS since it was approved in the U.S in 1996," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "AVONEX PEN has been shown to help reduce the anxiety patients may experience when self-injecting and for patients initiating treatment, titration can reduce the flu-like symptoms they may have when beginning AVONEX therapy."

AVONEX PEN is the first IM autoinjector approved in MS treatment. It was designed to enhance the self-injection process and features a substantially smaller needle than the AVONEX Prefilled Syringe. The U.S. Food and Drug Administration (FDA) approved the AVONEX PEN in February 2012 based on data from a Phase 3b study in which approximately nine out of 10 patients used the device successfully. In this study patients felt significantly less injection pain after they switched from the Prefilled Syringe to AVONEX PEN and the patients experienced reduced injection anxiety with AVONEX PEN than with the Prefilled Syringe. Ninety-four percent of patients in the study also expressed a preference for AVONEX PEN over the AVONEX Prefilled Syringe. The top three reasons for this preference were ease of injection, reduction in pain and reduction in injection anxiety.

"One of the key aspects of treating MS is helping patients manage their treatment in order to get the most out of their therapy," said Peter B. Wade, M.D., medical director at the Joyce D. and Andrew J. Mandell Center for Comprehensive Multiple Sclerosis Care and Neuroscience Research at Mount Sinai Rehabilitation Hospital in Hartford, Conn. "For many of my patients, AVONEX PEN will help reduce injection-related anxiety and improve the self-injection experience."

The recently-approved AVONEX titration schedule can be facilitated by the AVOSTARTGRIP kit, a set of three devices that work with the AVONEX Prefilled Syringe to administer the appropriate amount of medicine needed to titrate up to a full dose of AVONEX over the course of three weeks. The FDA approved this titration regimen in February 2012, based on data from an eight-week, randomized, healthy volunteer study. It showed that a three-week titration period at treatment initiation reduced the severity of flu-like symptoms associated with AVONEX treatment by 76 percent, as well as significantly reduced the incidence of flu-like symptoms, versus no titration four to six hours post-injection.

Patients who are new to AVONEX treatment have the option to initiate therapy with the AVOSTARTGRIP titration kit; once patients have completed the titration regimen, treatment can be continued with AVONEX PEN or other approved dosing options.

AVONEX PEN is available from the same pharmacies patients currently fill their AVONEX Prefilled Syringe prescriptions. Patients and healthcare providers who would like more information about AVONEX PEN or the AVOSTARTGRIP titration kit can visit [www.avonex.com](http://www.avonex.com).

### About AVONEX PEN

AVONEX PEN is the first single-use, once-a-week, fully integrated IM autoinjector for MS. It is designed for use with AVONEX treatment in patients with relapsing forms of MS. AVONEX PEN integrates the currently approved AVONEX Prefilled Syringe and incorporates a smaller needle (25 gauge, 5/8 inch), which is thinner and 50 percent shorter than the standard AVONEX Prefilled Syringe needle.

Additional features of AVONEX PEN include: a protective injector shield that conceals the needle prior to injection; automated needle insertion and medication delivery; and a diameter and length designed to stabilize AVONEX PEN during the injection procedure. In addition, AVONEX PEN incorporates a safety lock, which helps prevent injection error and a display window that confirms complete delivery of the medication.

The efficacy and safety of AVONEX PEN was evaluated in an open-label, multicenter, Phase 3b study (n=70). Efficacy was assessed through objective and subjective assessments of key aspects of patients' use of AVONEX PEN.

### About Titration

The AVONEX label provides physicians and patients with a clinically-supported schedule for gradually escalating the dose of AVONEX at the start of therapy, which has been shown to reduce the incidence and severity of flu-like symptoms that can occur with AVONEX treatment. In an eight-week, healthy-volunteer, randomized, Phase 1 study (n=234), a three-week titration period at the initiation of AVONEX treatment reduced the incidence (Odds Ratio: 0.18) of flu-like symptoms versus no titration four to six hours post-injection. It also reduced the severity of flu-like symptoms by 76 percent versus no titration four to six hours post-injection.

Titration with AVONEX can be facilitated by the AVOSTARTGRIP kit, a set of three devices that work with the AVONEX Prefilled Syringe to administer

three titrated doses of AVONEX over a three-week period: 7.5mcg, 15mcg and 22.5mcg. The full dose should be administered at week four.

A titration regimen should only be considered for patients initiating AVONEX therapy. Once patients have completed the titration regimen, treatment can be continued with AVONEX PEN or other administration options.

AVOSTARTGRIP titration kits are provided free of charge to patients who initiate treatment with AVONEX. For more information about services Biogen Idec provides for patients with MS, visit [www.MSActiveSource.com](http://www.MSActiveSource.com).

#### **About AVONEX**

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. AVONEX is indicated for the treatment of patients with relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with MS.

Symptoms of depression, suicidal ideation, or psychosis, and cases of suicide, have been reported with increased frequency with patients receiving AVONEX. Severe hepatic injury, including cases of hepatic failure has been reported rarely in patients. Rare cases of anaphylaxis have been reported. While beta interferons do not have any known direct cardiac toxicity, cases of congestive heart failure, cardiomyopathy, and cardiomyopathy with congestive heart failure have been reported in patients without known predisposition. Decreased peripheral blood counts have been reported from postmarketing experience. Seizures have been reported in patients using AVONEX, including patients with no prior history of seizure. Autoimmune disorders of multiple target organs have been reported. Routine periodic blood chemistry, hematology, liver function, and thyroid function tests are recommended. There are no adequate and well-controlled studies in pregnant women. AVONEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The most common side effects associated with AVONEX treatment are flu-like symptoms, including chills, fever, myalgia, and asthenia.

For additional important safety information, and the complete United States full prescribing information, please visit [www.AVONEX.com](http://www.AVONEX.com).

#### **About Biogen Idec**

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than \$5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit [www.biogenidec.com](http://www.biogenidec.com).

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