This story captures one individual’s experience with ITB Therapy. Results vary; not every individual will receive the same benefits. Side effects can occur. For complete prescribing information, please refer to the enclosed patient information.

Diana's Story of Living with Multiple Sclerosis

In 1993, Diana was diagnosed with multiple sclerosis. The first symptoms emerged as pain in her face and left arm, but over several years the multiple sclerosis progressed and symptoms made it hard for her to go about her daily activities. She found it difficult to walk and maintain her balance which caused her to fall to the ground on a number of occasions.

"I walked with a cane for 5 years. Some days I could walk sort of good, but most of the time I was much too spastic. It made me feel uneasy to have to walk that way, but then I was glad I could walk at all," Diana recalls.

Her tight, stiff muscles interfered with her independence. She and her husband, Doug, loved to play disc golf and go camping. Having to use a cane made it hard to set up camp and playing disc golf became an "exercise in futility." Even simple things took twice as long to do and tending her garden became very challenging.

Diana tried using oral medications to treat her spastic muscles, but they weren’t very effective and made her very drowsy. That is when Diana’s doctor suggested Medtronic ITB Therapy™ (Intrathecal Baclofen Therapy).

Overcoming an Obstacle

ITB Therapy relieves spasticity by using a programmable pump placed just under the skin of the abdomen. The pump is connected to a small, flexible catheter that delivers a liquid form of baclofen directly into the area where fluid flows around the spinal cord called the intrathecal space. Before Diana and her doctor made the decision whether or not to have the pump placed, she needed to have a screening test to see if the liquid baclofen would relieve her symptoms.

"Four hours after my screening test began, suddenly it was just like fluid motion; I could swing my leg from my hip," Diana remembers. "I was walking like I had been before I was diagnosed with MS; I could not believe it. I was crying, the nurses were crying, my doctor was crying. They couldn’t believe the difference.”

When Diana attempted to stand up soon after the test dose she experienced a headache caused by a spinal fluid leak. Diana and her doctor resolved this problem by giving her two injections and having her lay flat for several hours.

Diana had the pump placed in March of 2000. She spent three days recovering from her surgery in the hospital and spent another few weeks in physical therapy as an outpatient.

Since receiving ITB Therapy, Diana no longer needs a cane to assist her in walking. She has gotten back to doing the things that she loves, like gardening, camping, and accompanying her husband on disc golf tournaments. According to Diana, "ITB Therapy has made it a lot easier for my husband as my caregiver. I can’t play disc golf anymore, but I can walk with him on the courses and we are able to spend much more time together.”

"Walking with fluid motion again has made me feel so much better about myself. It’s wonderful.”

Diana S., living with multiple sclerosis, has been receiving Medtronic ITB Therapy™ since March 2000.
Completely read this information before you start using Medtronic ITB Therapy. This information does not take the place of thorough discussions with your doctor. You and your doctor should discuss ITB Therapy before you begin receiving the therapy and at regular refill appointments.

**Q: What is Lioresal® Intrathecal (baclofen injection)?**
A: Lioresal Intrathecal is a liquid form of baclofen, and is commonly used to treat severe spasticity. Liquid baclofen is used for injections and infusion into the intrathecal space (the fluid-filled area surrounding the spinal cord), using an implantable drug delivery system.

**Q: What is severe spasticity?**
A: Severe spasticity is tight, stiff muscles that make movements – especially of the arms and legs – difficult or uncontrollable. Severe spasticity can interfere with an individual's function and/or comfort.

**Q: Who is a candidate for Lioresal Intrathecal?**
A: People who suffer from severe spasticity resulting from cerebral palsy, multiple sclerosis, stroke, traumatic brain injury, or spinal cord injury, and who suffer intolerable side effects from oral baclofen (pills), may be a candidate for Lioresal Intrathecal. A screening test will help determine if you will respond to the intrathecal medication. Talk with your doctor about whether Lioresal Intrathecal may be an option for you.

**Q: Who is not a candidate for Lioresal Intrathecal?**
A: People who are hypersensitive (extremely sensitive) to oral baclofen should not take Lioresal Intrathecal.

**Q: What are the most common side effects of Lioresal Intrathecal?**
A: The side effects of intrathecal baclofen include loose muscles, sleepiness, upset stomach, vomiting, headaches, and dizziness. As with most medications, overdose (drug dose is too high) or under dose (drug dose is too low) can occur. Talk with your doctor about the side effects you may experience from your treatment.

**Q: What do I need to know if I am using Lioresal Intrathecal?**
A: Abruptly stopping intrathecal baclofen can result in serious medical problems and in rare cases has been fatal. It is important to keep your pump filled with medication by attending regularly scheduled refill appointments.

**Q: What are the signs of rapid or abrupt withdrawal from intrathecal baclofen?**
A: Increase or return in spasticity, itching, low blood pressure, lightheadedness, and tingling sensation are often early indications of baclofen withdrawal. It is very important that your doctor be called right away if you experience any of the above symptoms. In rare cases, severe symptoms may occur. These symptoms include high fever, altered mental status, spasticity worse than before you started ITB Therapy, and muscle rigidity. It is very important that your doctor be called right away if you experience any of the above symptoms.

**Q: What can I do to prevent baclofen underdose or abrupt discontinuation of intrathecal baclofen?**
A: It is very important that you keep all of your refill appointments. This may require some planning prior to traveling. Maintaining a regular refill schedule will ensure the pump does not run out of medication and that any potential problems with the infusion system are diagnosed and corrected. Additionally, you should be aware of what your pump alarms sound like. If you hear an alarm, contact your doctor immediately. Furthermore, it is very important that you know and understand the signs of baclofen underdose. Also be sure to tell your doctor right away if you experience any unusual symptoms, side effects, or changes in your condition.

**Q: What are the symptoms of baclofen overdose?**
A: Although rare, it is possible for you to receive too much medication (overdose). A baclofen overdose may cause drowsiness, lightheadedness, respiratory depression (difficulty breathing), seizures, loss of consciousness and coma. If you experience any of the above symptoms, it is very important that you or your caregiver contact your doctor right away.

This provides a summary of the most important information about Lioresal Intrathecal. If you would like more information, talk with your doctor. You can ask for information about Lioresal Intrathecal that is written for healthcare professionals. You also can get more information by visiting www.spasticity.com.

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