ITB THERAPY℠
Intrathecal Baclofen Therapy

For the management of severe spasticity

Information for you and your family
Committed to restoring people to full lives

With the invention of the pacemaker, Medtronic created a whole new industry based on medical technology. For more than 50 years, Medtronic has worked with physicians around the world to create products and therapies that alleviate pain, restore health, and extend life. In fact, Medtronic currently provides products and services that treat more than 5 million people each year. For more information about Medtronic, visit us online at www.medtronic.com.

Visit us online at www.spasticity.com

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This guide was designed to introduce you to Medtronic ITB TherapySM (Intrathecal Baclofen Therapy) and answer many of your questions. We hope you find it helpful. Words that appear in bold type are defined in the glossary at the back of this booklet. Your clinician can provide even more information and help you determine if ITB Therapy is right for you.

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* Please refer to the Lioresal® Intrathecal (baclofen injection) patient information on page 20 of this brochure.

This guide contains the experiences of several individuals with ITB Therapy. It is important to keep in mind that individual experiences vary. Not every individual will have the same results. Side effects can occur. For complete prescribing information please refer to page 20 of this guide.
About Medtronic ITB Therapy

ITB Therapy is Intrathecal Baclofen Therapy, a treatment option that delivers an injectable form of baclofen, Lioresal® Intrathecal (baclofen injection), directly to the fluid surrounding the spinal cord. The medication is delivered using a programmable pump that is surgically placed and connected to a catheter in the body. The medicine is delivered continuously based on the prescription programmed by your doctor. This method of drug delivery is called intrathecal infusion. The drug infusion system delivers the medication in small, precisely controlled doses throughout the day.

What makes ITB Therapy different from oral medications is the delivery of the medication to the site where it is used — the fluid-filled area surrounding the spinal cord called the intrathecal space. Intrathecal baclofen relieves severe spasticity with only small amounts of medication. Unlike oral medications, which circulate throughout the body in the blood (see systemic drug delivery), the drug is delivered where it is most effective. This may help minimize side effects, such as weakness, drowsiness, nausea, or other negative effects that often accompany oral baclofen or other medications. People who are extremely sensitive to oral baclofen are not candidates for ITB Therapy.

Because ITB Therapy delivers Lioresal Intrathecal directly to the spinal cord, it relieves spasticity with smaller amounts of medication than when taken orally. This helps minimize systemic side effects.

The information on the following pages may help you determine if this treatment option may be right for you or your loved one.

“*The pump has helped Shellie enjoy life again. She is happy, comfortable, and joyful.*”
— Alison, family caregiver/Shellie’s mom

Shellie S. | Person with a brain injury
Receiving ITB Therapy since 1997

Julie M. | Living with multiple sclerosis
Receiving ITB Therapy since 1996
Benefits of ITB Therapy
In studies, people have anecdotally reported that Medtronic ITB Therapy helped them to:

- be more independent, allowing them to feed or dress themselves\textsuperscript{6-9}
- sit more comfortably or transfer more easily\textsuperscript{6-9}

Additionally, caregivers have reported that care is easier with ITB Therapy\textsuperscript{6-9}

Furthermore, people receiving ITB Therapy and their caregivers have expressed high rates of satisfaction with the therapy. Consider these statistics:

- ITB Therapy demonstrated the highest patient satisfaction rating compared with all oral treatments.\textsuperscript{2}
- More than 94% of caregivers are satisfied with ITB Therapy.\textsuperscript{10}
- 81% of care providers "strongly agreed" that they would repeat the (pump) procedure.\textsuperscript{10}
- More than 80% of caregivers would recommend ITB Therapy to others.\textsuperscript{10}

ITB Therapy may be used to treat severe spasticity related to a number of conditions. Following is information on the effect of ITB Therapy on those conditions.

Stroke
- Studies have demonstrated that ITB Therapy has no effect on the unaffected side of the body.\textsuperscript{12}
- ITB Therapy results in improvement in walking speed, functional mobility, and spasticity.\textsuperscript{13}
- ITB Therapy significantly improves stroke survivors’ muscle tone, function, and quality of life.\textsuperscript{1}

Cerebral Palsy
- ITB Therapy results in improved function.\textsuperscript{14}
- Study results have shown that reduction in muscle tone with ITB Therapy may slow or prevent the development of hip problems, including dislocation.\textsuperscript{14}
- ITB Therapy helps facilitate improvements in self-care and social function.\textsuperscript{15}
- If ITB Therapy is offered at the appropriate time, orthopedic or neurologic surgery may be delayed or avoided altogether.\textsuperscript{16}
- ITB Therapy provides long-term control (>11 years) in spasticity of cerebral origin with side effects usually managed by dose adjustments.\textsuperscript{17}

Multiple Sclerosis
- ITB Therapy results in significant decrease in spasticity.\textsuperscript{18, 19}
- ITB Therapy results in improved function.\textsuperscript{19, 20}

Spinal Cord Injury
- ITB Therapy provides long-term control (>7 years), which can be achieved in most spasticity of spinal origin.\textsuperscript{21}
- ITB Therapy results in a reduction in spasticity and spasms.\textsuperscript{28}
- ITB Therapy has been shown to improve bowel and bladder performance.\textsuperscript{9, 22}
- Performance of activities of daily living (bathing, dressing lower body, transfers)\textsuperscript{8, 23} and quality of life\textsuperscript{24} improves with ITB Therapy, with a small number of significant complications.

Brain Injury
- ITB Therapy results in a significant reduction in spasticity and spasms, which leads to marked reduction in spasticity-related pain.\textsuperscript{26}
- With ITB Therapy, nursing and movement become much easier.\textsuperscript{26}
- ITB Therapy has been shown to reduce spasticity in both the upper and lower limbs.\textsuperscript{27}

Risks Associated with ITB Therapy
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 underdose (drug dose is too low) can occur. Talk with your clinician about the side effects you may experience from your treatment. For more information, please refer to the information on Lioresal Intrathecal on page 20 of this brochure.

Determining If ITB Therapy Is Right for You
A standard screening test determines if ITB Therapy may work for you. Your clinician will inject a small dose of Lioresal Intrathecal into the intrathecal space (where fluid flows around your spinal cord). If your muscles become looser, ITB Therapy may work effectively for you.

Your muscles will most likely relax when you receive the test dose of medication.

In clinical studies, a positive response to the screening test was demonstrated in:

- 97% of patients with spasticity of spinal origin—spinal cord injury, multiple sclerosis
- 86% of patients with spasticity of cerebral origin—brain injury, cerebral palsy
The Day of Your Screening Test

- Your clinician will review the screening test procedure with you in detail. Be sure to discuss any questions or concerns you may have.
- You will check into a medical facility for the screening test, either the night before or the day of the test. The screening test procedure includes injection of the medication followed by monitoring for several hours (usually 8 to 12 hours), depending on the facility's procedures.
- Before the procedure, your clinician might conduct a variety of tests to assess your spasticity and its impact on your ability to perform various tasks including activities important to your daily routine.
- Your clinician probably will numb a small area of your lower back. A small dose of the medication then will be injected into your intrathecal space, the area where fluid flows around your spinal cord. Only a small amount of medication is injected, but it is enough to have an effect in most people.
- The medication may take 30 minutes to 1 hour to begin to relax your muscles. You could begin to feel the medication's greatest effect about 4 hours after the injection, and the effect usually lasts 6 to 8 hours or more.
- After the effect of the medication wears off, you will return to the same amount of spasticity that you had before the screening test.

During the screening test, your clinician will regularly monitor your vital signs (pulse, respiration, blood pressure) and the amount of spasticity in your muscles. By measuring and comparing your spasticity before and during the screening test, you and your clinician will be able to see what effect the medication is having.

Everyone Responds Differently

Everyone responds differently to the test dose. The medication probably will relax your muscles. Your muscles may loosen only slightly, or your muscles might feel so completely loose or weak that you can’t use them, especially your legs. Either response simply means that ITB Therapy may work for you.

If your muscles do become completely loose, it is important to realize that this is temporary and usually not cause for concern. This weakness happens when you receive the medication all in one dose rather than gradually throughout the day as a pump would deliver the dose. The effect is temporary. When the effect of the medication wears off, you will return to the same amount of spasticity you had before the screening test.

During the screening test, these temporary side effects are possible:

- Overly loose muscles
- Headache
- Sleepiness
- Dizziness
- Nausea/vomiting

Be sure to tell your clinician if you experience any of these possible side effects.

If you decide to go on to receive ITB Therapy, you and your clinician will work together to adjust the pump to manage your spasticity by delivering the dose of medication that’s just right for you.

For more information about the screening test, ask your clinician for a copy of the ITB Therapy screening video.

What Happens After the Standard Screening Test?

After your screening test is complete, you and your clinician will discuss your results and determine if you are a candidate for ITB Therapy.

Sometimes people don’t respond to the first test dose of medication. If this happens, your clinician may give you a second test dose using the same procedure. The second dose may be given the next day, or the procedure may be rescheduled for another time. If this still does not loosen your muscles, your clinician may give you an even larger dose. If this dose does not loosen your muscles, you likely are not a candidate for ITB Therapy.

Please discuss any questions you may have with your clinician and be sure to discuss the long-term benefits and risks of ITB Therapy.

“After she got the pump, it became much easier for Ali to move around in physical therapy.”

– Debby, family caregiver/Ali’s mother

Ali G. | Living with cerebral palsy
Receiving ITB Therapy since 1993
If ITB Therapy Is Right for You

If you and your clinician decide ITB Therapy is right for you, you will be scheduled to receive a Medtronic SynchroMed® Programmable Drug Infusion System.

The SynchroMed System offers a fully implantable and programmable method of continuous drug delivery. In use clinically since 1982, and commercially since 1988, the programmability of the SynchroMed system allows:

- Dosages to be varied throughout the day and tailored to match your individual medication needs.
- The potential for doses lower than would be needed with oral medications, which may result in reduced side effects.
- Non-invasive dose changes.

The SynchroMed System consists of:

- Implantable pump
- Implantable catheter
- External programmer

“\textit{When I got the pump, everything became easier. Getting dressed only takes about five minutes, and I do it by myself.}”

— T.J.F. | Living with spinal cord injury
Receiving ITB Therapy since 1989

**SynchroMed Pump:** The SynchroMed pump is an implantable, battery-powered device that stores and dispenses medicine according to instructions provided by your clinician.

**Intrathecal Catheter:** The intrathecal catheter is a thin, flexible tube that connects to your programmable pump and delivers medication from the pump to the area where fluid flows around the spinal cord — called the intrathecal space.

**Medtronic Programmer:** Your clinician will use a programmer during your refill and checkup sessions. The programmer is the external component of the SynchroMed System. The programmer allows your clinician to communicate with your SynchroMed pump and program it to deliver the right amount of medicine.

**Surgery**

The SynchroMed System is placed during a surgical procedure that may require a brief hospital stay. During the surgery, the pump is placed just under the skin of your abdomen and connected to the catheter.

As with any surgical procedure, complications may occur after the pump is placed. Since the pump and catheter are placed beneath the skin, infections can develop and are generally related to the healing of the surgical incision, not to the long-term use of ITB Therapy.

In addition to surgical complications, there is potential that you may experience:

- Side effects caused by the medications used in the pump
- Symptoms of drug overdose
- Symptoms of drug underdose

Talk with your clinician about the potential side effects and complications associated with your medication and surgical procedure.
**Post-Surgery Care**

After surgery, there will be some discomfort and tenderness where your programmable pump and catheter for ITB Therapy are placed. Your clinician may prescribe medication to relieve the pain caused by surgery and antibiotics to prevent infection. If you notice any swelling, pain, or redness near your incision, notify your clinician.

Your clinician may recommend that you restrict activity for six to eight weeks after surgery. Once your incision has healed, the pump site requires no special care. However, you should talk with your clinician if you perform any excessive or repetitive activities that may damage your programmable pump and catheter.

**Device-Related Events**

The programmable pump is designed to automatically deliver your medication at the rates and amounts you and your clinician determine best meet your needs.

Problems with the pump and catheter for ITB Therapy may result in:
- Return or increase in spasticity.
- Drug withdrawal symptoms (please refer to information on Lioresal Intrathecal on page 21).
- Need for surgical removal of the pump or catheter adjustment.
- Delivery of medication into the area under your skin where the programmable pump is placed or along the catheter path.

Talk with your clinician about any additional complications associated with your treatment.

**Therapy Maintenance**

The key to effective therapy management is active involvement and cooperation with your clinician. One of your most important responsibilities is to ensure the maintenance of the pump by making regular return visits to your clinic for follow-up care.

The frequency of follow-up visits varies from weeks to months, depending on the dose of your medication. These short visits are necessary to have your programmable pump refilled with medicine and the prescription adjusted. Your clinician will also check the pump to make sure it is working properly. During a typical session, the programmable pump will be emptied and refilled by a needle inserted through your skin. This is a relatively short and painless procedure.

It is important to keep and attend all of your refill appointments to maintain the level of medication you need for continuous and effective therapy and to monitor the performance and battery levels of your programmable pump. The battery lasts several years. The battery life depends on how much medicine you are programmed to receive each day. Before the battery runs out, you will need to replace your pump with a new one through a surgical procedure. The catheter usually can stay in place and be reconnected to the new programmable pump. Furthermore, it is very important that you know and understand the signs of baclofen withdrawal (see page 21). Be sure to tell your clinician right away if you experience any unusual symptoms, side effects, or changes in your condition.

“ItB Therapy isn’t saving my life, but it helps me live my life without worrying about my disability. In a sense, that is saving my life.”

– Jason F. | Living with spinal cord injury
Receiving ITB Therapy since 1991

“The pump has brought back my life to me. My husband and I can do things on the weekends that we couldn’t do before the pump. I can go to a movie and walk into the theater without a cane. I have the stamina to go out for dinner with friends.”

– Pam B. | Living with multiple sclerosis
Receiving ITB Therapy since 2004
What Is Your Role in Making ITB Therapy Work?
When receiving ITB Therapy, it is very important for you to follow your clinician’s instructions. You should also:
- Carry your patient ID card and emergency cards with you at all times.
- Always keep your follow-up and refill appointments.
- Tell your clinician if you don’t feel well or if you are having problems with the programmable pump.
- Immediately notify your clinician if you hear a pump alarm.
- Learn the programmable pump name (SynchroMed) and model number and the name of the medication used in the pump — Lioresal Intrathecal.
- Tell your other clinicians and your dentist about ITB Therapy.
- Make sure your family and friends know about the programmable pump, so they can help in an emergency.
- If you plan to travel, tell your clinician so she or he can make sure enough medicine is in your programmable pump.

Creating New Possibilities
By reducing your severe spasticity, ITB Therapy may create some new possibilities for you. For example, you may be able to participate more fully in rehabilitation therapies, such as physical and occupational therapy. Combining these therapies with ITB Therapy may allow you to achieve new and different goals that were unattainable due to severe spasticity.

Intensive physical therapy (3–5 times per week) may begin 6–8 weeks after you start receiving ITB Therapy. Regardless of whether you have undergone therapy before your surgery, you may be able to make significant advances that were not previously possible.

“ITB Therapy has given me independence to continue doing the things I’ve always enjoyed.”
— Mary C. | Stroke survivor Receiving ITB Therapy since 2003

“I know the difference [the pump] has made in my child’s life. He’s doing so many things that he may not have been able to do had he not had this opportunity.”
— Eve, family caregiver/Nick’s mom

Nick C. | Living with cerebral palsy Receiving ITB Therapy since 1999
Spasticity ... You Can Do Something About It

With ITB Therapy, you may be able to improve functional abilities and your quality of life. Discuss any questions you have with your health care team. Talk to your clinician about the potential long-term benefits and possible risks associated with ITB Therapy.

ITB Therapy is available by prescription only. Please refer to the information on Lioresal Intrathecal on page 20, or visit www.spasticity.com for complete prescribing information.

What is spasticity?

Spasticity is tight, stiff muscles that make movement — especially of the arms and legs — difficult or uncontrollable. Sometimes spasticity is so severe that it gets in the way of daily activities, sleep patterns, and caregiving, and can even threaten people’s safety.

What is ITB Therapy?

ITB Therapy is Intrathecal Baclofen Therapy, a unique treatment that delivers a liquid form of baclofen, called Lioresal Intrathecal, directly to the fluid surrounding the spinal cord. The medication is delivered in small, precisely controlled doses using a programmable pump and catheter that are surgically placed.

Can you tell me more about the pump?

The programmable pump is surgically placed, usually just under the skin of the abdomen. The device is round and metal and 74 mm in diameter. Most people report that the programmable pump is not uncomfortable or restrictive and does not interfere with their movement. Depending on your size and shape, it may not show at all under regular clothes.

Does the pump run out of medication?

Your programmable pump needs to be refilled with medication periodically, using an external procedure performed in your clinician’s office.

Refill dates are scheduled based on:

- The amount of medication your programmable pump holds.
- The concentration of the medication you are receiving.
- The rate at which the pump delivers medication.
- The frequency of dosing changes required by your particular treatment plan.

Embrace the Possibilities

If you have questions, or would like additional information, you may wish to take advantage of some of our resources:

- For more information on ITB Therapy, visit: www.spasticity.com or call 1-800-856-3823.
- Talk with your clinician about ITB Therapy.
- Visit www.exploringspasticity.com for resources and information on spasticity.

Common Questions

For additional information about ITB Therapy, visit www.spasticity.com.

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- The amount of medication your programmable pump holds.
- The concentration of the medication you are receiving.
- The rate at which the pump delivers medication.
- The frequency of dosing changes required by your particular treatment plan.
What happens if the programmable pump runs out of medication?
Abruptly stopping Lioresal Intrathecal can result in serious medical problems and in rare cases has been fatal. For more information, please refer to the information on Lioresal Intrathecal on page 21 of this brochure.

How long does a refill procedure take?
The average time varies from clinic to clinic, depending on their procedures. However, on average, a refill appointment lasts about 30–45 minutes. During the refill procedure, your clinician will place a plastic template on your skin, over the area where your pump is implanted. This template will help him or her locate the refill port on your pump. Your clinician will refill your pump by inserting a needle through your skin into your pump.

How do I know if ITB Therapy will work for me?
To determine whether you are a candidate for ITB Therapy, your clinician will give you a screening test. A small dose of Lioresal Intrathecal is injected into the intrathecal space (where fluid flows around the spinal cord). Then your clinician will see how much your muscles relax over the next 6 to 8 hours.

Will ITB Therapy cure my spasticity?
No, ITB Therapy is used to manage severe spasticity but cannot take away its cause. ITB Therapy is not a cure for spasticity or the conditions that are associated with it.

If oral baclofen didn’t work for me, why would ITB Therapy work?
ITB Therapy delivers a liquid form of baclofen, Lioresal Intrathecal, directly into the intrathecal space, where fluid flows around the spinal cord. ITB Therapy relieves severe spasticity with small amounts of Lioresal Intrathecal delivered via a programmable pump that is surgically placed and connected to a catheter in the body. What makes ITB Therapy different from oral medications is the delivery of the medication to the fluid-filled area surrounding the spinal cord. Because the drug is delivered directly to where it is needed in the spinal fluid, only minimal amounts circulate throughout the body in the blood. This helps minimize the possible side effects that often accompany oral medications.

What if I need some spasticity for transfers, walking, or standing?
Will ITB Therapy take this away?
Your clinician can program the SynchroMed pump to deliver the precise amount of medication that you need. It can even be set to deliver different amounts at different times of the day, if needed. For example, the pump can be set to deliver less medication in the daytime when you may rely on your stiffness to walk, transfer, or put on clothes, then automatically deliver more medication at night to reduce spasticity to help you sleep.

Will ITB Therapy improve my comfort or physical ability?
It is important to note that this therapy cannot give you any abilities that you do not already have. It may, however, relieve the spasticity that often prevents individuals from using these abilities or realizing their full potential. Appropriate goal-setting with your clinician is a key to satisfaction with your treatment regimen.

In studies, people have anecdotally reported that Medtronic ITB Therapy helped them be more independent, allowing them to feed or dress themselves, sit more comfortably, or transfer more easily.\textsuperscript{6–9}

Additionally, caregivers have anecdotally reported that care is easier with ITB Therapy\textsuperscript{6–9} and they have "reported a reduction in use of oral medication for spasticity, and improvements in comfort, function, and ease of care."\textsuperscript{10}

Can I stop taking other medications once I have a pump?
Your clinician will determine if you still need to take other medications.

How will alcohol or other medications affect me?
The drowsy effect of Lioresal Intrathecal may add to the effect of alcohol or other depressants. Drowsiness has been reported in patients receiving Lioresal Intrathecal. You should be careful driving, operating dangerous machinery, or taking part in activities that may be dangerous if you are not alert.

Does the SynchroMed pump or Lioresal Intrathecal affect sexual function?
There have been reports of patients who have been affected. This usually is not permanent and may be helped by changing the dose of Lioresal Intrathecal.
On average, how long does the surgery take?
Times vary depending on individual surgical techniques. On average, the procedure takes one to two hours from start to finish. Talk with your clinician about specifics and duration of your procedure.

Is ITB Therapy covered by insurance?
ITB Therapy is an FDA-approved, commercially available treatment and is covered by most health insurance companies, Medicare, and most state Medicaid programs for the approved indications. Talk to your clinician, insurance agent, or benefits manager if you have questions.

What are the most common side effects of Lioresal Intrathecal?
The side effects of Lioresal Intrathecal include loose muscles, sleepiness, upset stomach and vomiting, headaches, and dizziness. Talk to your clinician about the possible side effects you may experience from your treatment. For more information about Lioresal Intrathecal, please refer to page 20 of this brochure, or visit www.spasticity.com.

For stroke survivors, will ITB Therapy affect the "good" side?
In a clinical study, no objective or subjective motor weakness was noted on the unaffected (or "good") side.1 12

Can I undergo MRI testing?
Contact your clinician before having Magnetic Resonance Imaging (MRI) performed. Your clinician will recommend whether or not an MRI is appropriate for you.

Programmable pump performance has not been established for Magnetic Resonance Imaging (MRI) scanners at fields greater than 1.5 T (Tesla) scanners. Patients with ITB Therapy should not have an MRI using these scanners.

The MRI will cause your programmable pump to temporarily stop and suspend drug delivery during the MRI. The MRI may also cause your programmable pump to temporarily sound an alarm. This is normal with an MRI. The pump should resume normal operation after the MRI is complete. The effects of temporary suspension of medication will depend on the medication used in your programmable pump. Your clinician will determine if alternative delivery methods for the drug should be used during the time required for the MRI and if medical supervision should be provided while the MRI is conducted. Your clinician should check your programmable pump after an MRI to confirm it is still working properly.

During an MRI, you may notice a warming sensation around the programmable pump or feel a tingling sensation. If the warming or tingling sensation is uncomfortable to you, the MRI should be stopped and the settings adjusted to reduce or eliminate the sensation. During an MRI, you may also notice a slight tugging sensation at the pump. An elastic garment or wrap will reduce the tugging sensation. Additionally, the metal in the programmable pump may cause the MRI image to be distorted in the area around the pump. The MRI should be adjusted to minimize the image distortion.

Can I have a diagnostic ultrasound?
Electromagnetic interference (EMI) from diagnostic ultrasound (e.g. carotid scan, doppler studies) is unlikely to affect your SynchroMed pump.

Note: to minimize potential image distortion, the transducer must be kept 15 cm (6 in) away from the infusion system.

Will the use of a cellular phone affect my pump?
Your programmable pump is protected from low-powered stray electromagnetic interference (EMI) that is present in a typical cellular phone. However, if your phone is near your programmable pump (1 meter), be sure to turn your phone OFF prior to any telemetry on your pump to help prevent EMI. Some cellular phones (not all kinds) contain a tiny magnet.

Will a microwave oven affect my pump?
The programmable pump has built-in features to protect it from interference produced by electrical devices found in the household. Under normal conditions, the household appliances you use in your daily activities will not affect the programmable pump.

Be sure to keep all household appliances in good working condition. If you suspect interference with your programmable pump, move away from or turn off the electrical device. The programmable pump will not be permanently affected.
**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.

Rx only.

**Lioresal®** is a registered trademark of Novartis Pharmaceuticals Corporation

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.
baclofen injection: generic name for Lioresal Intrathecal, which is the drug used in the SynchroMed pump to manage spasticity.

brain injury: damage to the brain, such as that due to a severe hit in the head.

catheter: a flexible, silicone tube that connects to the pump. The pump delivers medication through the catheter to a specific area in the body.

cerebral: of the brain.

cerebral palsy (CP): a movement and posture disorder due to an injury or defect to the developing brain (brain damage).

drug infusion system: a system consisting of a pump and catheter, both of which are fully implanted and used to deliver medication. Programmable systems also feature an external programmer that is used to adjust the amount of medication the pump delivers.

intrathecal infusion/intrathecal drug delivery: the delivery of medication directly to the intrathecal space. This type of therapy can be administered with a fully implantable drug infusion system and is used to treat chronic pain or manage severe spasticity.

intrathecal space: area surrounding the spinal cord filled with cerebrospinal fluid.

ITB Therapy: treatment for spasticity using the SynchroMed Drug Infusion System (drug pump) that delivers Lioresal Intrathecal to the spinal cord.

Lioresal Intrathecal: the brand name for liquid baclofen.

multiple sclerosis: multiple sclerosis (MS) is a chronic, often disabling, disease of the central nervous system.

occupational therapy: involves adapting your physical environment to meet your needs (e.g., modifications for dressing, feeding, and grooming; creating an accessible home or workplace; or advising on the use of adaptive devices such as wheelchairs and bath equipment).

physical therapy: exercises that help stretch muscles, maintain mobility, and reduce the potential for injury. These exercises are designed to reduce muscle tone, maintain or improve range of motion and mobility, increase strength and coordination, and improve comfort.

programmable pump: round, metal disk that stores and releases liquid medicine at a rate that is programmed by a doctor.

programmer: the handheld computer used by doctors to adjust the amount of medication delivered by the SynchroMed programmable pump. The programmer uses radio frequency waves to communicate with implanted pumps.

refill: to take out old drug and fill the pump with new drug.

reservoir: area inside the pump that holds the medicine.

screening test: the clinician gives the patient a small dose of Lioresal Intrathecal to see how well it works prior to pump placement.

side effect: a result of drug or other therapy in addition to or in extension of the desired therapeutic effect: usually, but not necessarily, connoting an undesired effect.

spasticity: tight, stiff muscles.

spinal cord: column of nerve tissue in the spine that carries messages between the brain and the body.

spinal cord injury: an injury to the spinal cord that disrupts communication between the brain and other parts of the body, preventing messages from flowing past the damaged area.

stroke: a stroke, or brain attack, occurs when a blood clot blocks a blood vessel or artery, or when a blood vessel breaks, interrupting blood flow to an area of the brain. When a brain attack occurs, it kills brain cells in the immediate area.

SynchroMed Programmable Drug Infusion System: a programmable pump is placed just under the skin of the abdomen and is connected to a small, flexible catheter to deliver Lioresal Intrathecal directly into the area where fluid flows around the spinal cord. The system includes a fully implantable pump, a catheter, and a programmer that is used by clinicians.

systemic drug delivery/systemic therapies: treatments that carry medication throughout the entire body, rather than to a specific location. Some examples of systemic treatments include oral medications, IV treatments, and patches. By contrast, site-specific drug delivery delivers the medication only to the site where it is needed most.

test dose: single dose of Lioresal Intrathecal given during the screening test.
Lioresal® is a registered trademark of Novartis Pharmaceuticals Corporation.

References


“Because the spasticity has been reduced with ITB Therapy, I stretch better and am developing more range of motion. I look forward to getting more functional as time goes by.”

– Ed R. | Stroke survivor
Receiving ITB Therapy since 2004
For additional information about ITB Therapy, visit www.spasticity.com.