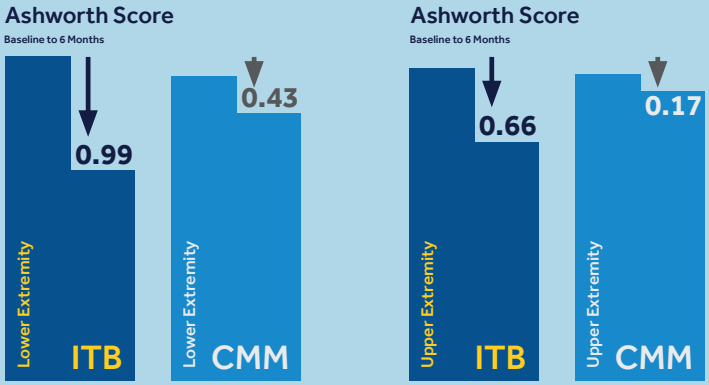
REDUCE POST-STROKE SEVERE SPASTICITY **OPTIMIZE FUNCTIONAL OUTCOMES**

New level-one evidence shows superior efficacy of ITB Therapy℠ compared to oral medication

SISTERS Key Findings with ITB Therapy℠

Statistically significant decrease in Ashworth score in **upper** and **lower** extremities compared to the oral medication



Function:

- Positive trend for improvement in the FIM at 6 months compared to CMM (p = 0.0540)
- ITB arm improved (2.68) while the CMM arm had a worsening FIM score (-2.58) at 6 months

Safety:

- More adverse events were reported in the implanted group (ITB) vs the CMM group
- Adverse events related to drug or device were generally expected as well-known secondary effects of spasticity or ITB Therapy℠
- No patients discontinued ITB Therapy℠ due to treatment-related adverse events

ITB Therapy℠ can make a difference for post-stroke severe spasticity. Results may vary. Download the manuscript from the Journal of Neurology, Neurosurgery and Psychiatry to learn more at ***sistersstrokestudy.com***

Please see additional important safety information, on the reverse side. For more information, please refer to the Lioresal® Intrathecal (baclofen injection) prescribing information and SynchroMed™ II brief statement on the reverse side.

Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure, and death. Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g., spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information (see WARNINGS).

Medtronic
Further, Together

Reference

1. Creamer M et al. Intrathecal baclofen therapy versus conventional medical management for severe post-stroke spasticity: results from a multicentre, randomised, controlled, open-label trial (SISTERS). *J Neurol Neurosurg Psychiatry.* Published online Jan 2018. Doi: 10.1136/jnnp-2017-317021

Important Safety Information for ITB Therapy℠ with Lioresal® Intrathecal (baclofen injection)
ITB Therapy℠ (Intrathecal Baclofen Therapy) is indicated for use in the management of severe spasticity. Patients should first respond to a screening dose of intrathecal baclofen prior to consideration for long term infusion via an implantable pump. For spasticity of spinal cord origin, ITB Therapy℠ via an implantable infusion system should be reserved for patients unresponsive to oral baclofen or those who experience intolerable CNS side effects at effective doses. Patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long term intrathecal baclofen therapy.

Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g., spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information (see WARNINGS).

This therapy is contraindicated in patients who are hypersensitive to baclofen. Implantation of the infusion system is contraindicated if the patient is of insufficient body size, requires a pump implant deeper than 2.5 cm, or, in the presence of spinal anomalies or active infection.

The most frequent drug adverse events vary by indication but include: hypotonia (34.7%), somnolence (20.9%), headache (10.7%), convulsion (10.0%), dizziness (8.0%), urinary retention (8.0%), nausea (7.3%), and paresthesia (6.7%). Pump system component failures leading to pump stall, or dosing/programming errors may result in clinically significant overdose or withdrawal. Acute massive overdose may result in coma and may be life-threatening.

The most frequent and serious adverse events related to device and implant procedures are catheter dislodgement from the intrathecal space, catheter break/cut, and implant site infection including meningitis. Electromagnetic interference (EMI) and magnetic resonance imaging (MRI) may cause patient injury, system damage, operational changes to the pump, and changes in flow rate.

Please refer to the full Lioresal® Intrathecal prescribing information and the SynchroMed™ II Drug Infusion System information for details.
Rev. 06/2018

SynchroMed™ II Drug Infusion System Brief Statement:

Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure.

Indications: US: Chronic intrathecal infusion of Infumorph® preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, Prialt® chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

Drug Information: Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration, screening procedures, and under-/overdose symptoms and methods of management. Patients should be informed of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions, and signs and symptoms that require medical attention.

Contraindications: System implant is contraindicated in the presence of an infection; implant depth greater than 2.5 cm below skin; insufficient body size; and spinal anomalies. Use of the system with drugs with preservatives and drug formulations with pH ≤3. Use of CAP kit for refills or of refill kit for catheter access and use of PTM to administer opioid to opioid-naïve patients or to administer ziconotide.

Warnings: Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose.

An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation. Monitor patients appropriately after refill if a pocket fill is suspected. Failure to recognize signs and symptoms of pocket fill and seek appropriate medical intervention can result in serious injury or death. Overinfusion may lead to underdose or overdose symptoms. Strong sources of electromagnetic interference (EMI), can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. The SynchroMed II system is MR Conditional; consult the labeling for MRI information.

Precautions: Monitor patients after pump or catheter replacement for signs of underdose/overdose. Infuse preservative-free saline at minimum flow rate if therapy is discontinued for an extended period of time to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions. EMI from the SynchroMed programmer may interfere with other active implanted devices (e.g., pacemaker, defibrillator, neurostimulator).

Adverse Events: In addition to procedure-related risks, the following may occur: pocket seroma; hematoma; erosion; infection; pump inversion; post-lumbar puncture risks (spinal headache); CSF leak and rare central nervous system pressure-related problems; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; allergic response to implant materials; surgical replacement due to end of service life or component failure; loss of therapy, drug overdose, or inability to program the pump due to component failure; catheter complications resulting in tissue damage or loss of or change in therapy; potential serious adverse effects from catheter fragments in intrathecal space.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com

Infumorph® is a registered trademark of West-Ward Pharmaceutical. Prialt® is a registered trademark of Jazz Pharmaceuticals plc or its subsidiaries. Lioresal® is a registered trademark of Saol.

USA Rx Only

Rev 0817

Lioresal® Intrathecal (baclofen injection) prescribing information

If missing, please visit medtronic.com/itbsafety.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000

medtronic.com