If a patient receiving ITB TherapySM (Intrathecal Baclofen Therapy) presents with the signs and symptoms suggestive of baclofen withdrawal (above), the following approach is consistent with that suggested by a panel of therapy-experienced clinicians convened to explore this issue:

1. Immediately contact a physician experienced in ITB Therapy, preferably the physician managing the therapy for the patient in question; follow the recommendations of this physician. This step is important even if the patient’s signs and symptoms seem mild.

2. If an ITB Therapy physician is unavailable, consider one or more of the following options, unless otherwise contraindicated:
   - high-dose oral* or enteral baclofen
   - restoration of intrathecal baclofen infusion
   - intravenous benzodiazepines by continuous or intermittent infusion, titrating the dosage until the desired therapeutic effect is achieved

   *Note: Oral baclofen should not be relied upon as the sole treatment for intrathecal baclofen withdrawal syndrome.

Baclofen withdrawal has been identified during post-approval use of Lioresal® Intrathecal (baclofen injection). Because this reaction is reported spontaneously from a population of uncertain size, it is not possible to reliably estimate the frequency.

Abrupt withdrawal of intrathecal baclofen, regardless of the cause, has, in rare cases, resulted in a life-threatening syndrome that included high fever, altered mental status, exaggerated rebound spasticity and muscle rigidity that progressed to rhabdomyolysis, multiple organ-system failure, and death.

All patients receiving ITB Therapy are potentially at risk. Some clinical characteristics of the advanced intrathecal baclofen withdrawal syndrome may resemble autonomic dysreflexia, sepsis, malignant hyperthermia, and neuroleptic-malignant syndrome.

A rapid and accurate diagnosis is important in an emergency room or intensive care setting before initiating treatment in order to prevent the potentially life-threatening central nervous and systemic effects of intrathecal baclofen withdrawal.

Contact Information
ITB Therapy™ Physician
Name: __________________________ Phone: __________________________
City: __________________________ State: __________________________

Refer to the drug manufacturer’s package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.


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