



**Gablofen**<sup>®</sup>  
(baclofen injection)

**Gablofen**<sup>®</sup>: Your On-Label Choice for the  
Medtronic SynchroMed<sup>®</sup> II Programmable Pump



**Gablofen**<sup>®</sup>  
(baclofen injection)



## The True Value of Gablofen<sup>®</sup>

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Gablofen<sup>®</sup> is an on-label FDA-approved intrathecal baclofen (ITB) studied and approved for use in the Medtronic SynchroMed<sup>®</sup> II Programmable Pump system. While there are generic ITB options that have FDA approval, they have not been studied in the SynchroMed II pump. Gablofen is the market share leader in the U.S. for ITB use and has been proven safe and effective through more than 10 years of intrathecal applications.

For clinicians and patients alike, Gablofen is the only on-label ITB option to offer the beneficial features of safety, convenient packaging, and helpful service offerings all rolled into one.

To learn more about Gablofen and its applications, visit **[Gablofen.com](https://www.gablofen.com)**.

To learn more about our educational opportunities, go to  
**[Gablofen.com/Providers/Education-Programs](https://www.gablofen.com/Providers/Education-Programs)**.





## Safe for Patients & Clinicians

A trusted name means peace of mind for patients and clinicians alike.



1.

Manufactured in the United States with a high level of sterility

2.

Studied and approved for use in the Medtronic SynchroMed® II pump system  
*(Using Off-Label drugs can increase the risk of pump failure and pose a risk to human life<sup>1</sup>)*

3.

Comes in precise amounts, reducing the risk of over-filling or under-filling the continuous infusion pump

4.

No breaking of glass ampules—a key element by reducing possible sharps injuries<sup>2</sup>

1. Medtronic 2020 Product Performance Report

2. Bloodborne Pathogens and Needlestick Prevention [Internet]. 2012 [Cited 16 Aug 2018]; Available from: <https://www.osha.gov/SLTC/bloodbornepathogens/evaluation.html>



# Packaging that Makes Sense

Our sensible packaging solves challenges and saves time.

- Comes in three concentration levels to optimize drug delivery
  - 500 mcg/mL
  - 1,000 mcg/mL
  - 2,000 mcg/mL
- Available in easy-to-use, 20 mL prefilled syringes
  - Drug and drug pathway are sterile
  - No need to draw or measure
  - Reduces the number of steps and preparation time
  - Labeled and color coded by concentration
- Available in factory-sealed vials
  - No breaking required, as with glass ampules
- Available for procurement directly from Piramal Critical Care or through major drug wholesalers
  - Pricing available through individual customer agreements, GPO contracts, 340B, and government contracts when applicable

Manufactured in a 50 mcg/mL prefilled test dose syringe



## Simplify the Pump Refill Process

A complimentary Pump Refill Convenience Kit that contains supplies for a 20 mL or 40 mL refill is included with EACH order.

- Designed by physicians for physicians for use with Gablofen® pre-filled syringes and vials
- Kit comes with everything you need for a pump refill—including a pump template, ChloroPrep™ antiseptic, and an individually wrapped pair of sterile, latex-free gloves
- Drug packaged separately from other kit contents to accommodate storage needs, either on the shelf or in an automatic dispensing unit (ADU) system



8500 KIT



9000 KIT



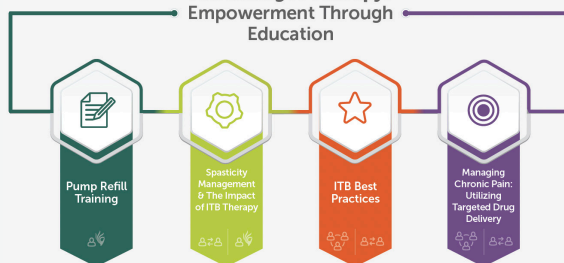


## More than a Product

Our products come with a partnership that adds value to your purchase.

- We offer a robust training and support network at no extra cost
- Seminars are conducted by Piramal Critical Care representatives and physicians from our Speaker's Bureau
- A dedicated product website makes safety and prescribing information available at all times
- First class customer service

### Advancing IT Therapy: Empowerment Through Education



Our customer education program offers informational sessions on ITB Therapy that can help grow your practice.

Visit [Gablofen.com/virtual](https://Gablofen.com/virtual) to learn more.

## INDICATIONS AND USAGE

- Gablofen® (baclofen injection) is a gamma-aminobutyric acid (GABA) ergic agonist indicated for use in the management of severe spasticity of cerebral or spinal origin in adult and pediatric patients age 4 years and above.
- Gablofen should be reserved for patients unresponsive to oral baclofen therapy, or those who experience intolerable central nervous system side effects at effective doses.
- Patients should first respond to a screening dose of intrathecal baclofen prior to consideration for long term infusion via an implantable pump.
- Spasticity due to traumatic brain injury: wait at least one year after injury before considering Gablofen therapy.

## IMPORTANT RISK INFORMATION

### WARNING: DO NOT DISCONTINUE ABRUPTLY

See full prescribing information for complete boxed warning

**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 post-implant clinician and patient information.**

## CONTRAINDICATIONS

- Hypersensitivity to baclofen.
- Do not use Gablofen for intravenous, intramuscular, subcutaneous or epidural administration.

## WARNINGS AND PRECAUTIONS

- Risk of life-threatening overdose during pump refills. Use extreme caution when filling the Medtronic SynchroMed® II Programmable Pump which is equipped with an injection port that allows direct access to the intrathecal catheter. Direct injection into the catheter through the catheter access port may cause a life-threatening overdose.
- Use only with Medtronic SynchroMed II Programmable Pump (or other pumps labeled for intrathecal administration of Gablofen (baclofen injection)).
- Potential for contamination due to non-sterile external surface of prefilled syringe. Although the drug solution and pathway in the Gablofen prefilled syringes are sterile, the external surface of the prefilled syringes (all strengths, including the 50 mcg/mL strength) are non-sterile and have the potential to lead to contamination and consequent adverse reactions. The use of Gablofen prefilled syringe in an aseptic setting (e.g., operating room) to fill sterile intrathecal pumps prior to implantation in patients is not recommended, unless the external surface of the prefilled syringe is treated to ensure sterility. Gablofen supplied in vials may be used with conventional aseptic technique to fill intrathecal pumps prior to implantation.
- Resuscitative equipment and trained staff must be available during screening dose, dose titration, and refills due to the potential life-threatening CNS depression, cardiovascular collapse, and/or respiratory failure.

- Overdose may cause drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia and loss of consciousness progressing to coma.
- Use with caution in patients with psychotic disorders, schizophrenia or confusional states as it may exacerbate condition(s).
- Fatalities have been reported with intrathecal baclofen use.
- Caution should be used in patients with a history of autonomic dysreflexia.
- Presence of infection may increase the risk of surgical complication and complicate dosing of Gablofen.
- May cause drowsiness: use caution in operation of automobiles, dangerous machinery and activity that may be hazardous by decreased alertness. Other CNS depressants and alcohol may add to this effect.
- Potential development of intrathecal mass formation. Clinicians should monitor for signs and symptoms of new neurologic symptoms including the use of imaging diagnostic modalities.
- Oral baclofen use has been associated with a dose-related increase in incidence of ovarian cysts.

## ADVERSE REACTIONS

### SERIOUS ADVERSE REACTIONS

- Sudden withdrawal of Gablofen can result in serious complications that include high fever, confusion, muscle stiffness, multiple organ-system failure, and death. Inform patients that early symptoms of Gablofen withdrawal may include increased spasticity, itching, and tingling of extremities. If Gablofen withdrawal or a pump malfunction is suspected, patients should be brought immediately to a hospital for assessment and treatment.
- Gablofen overdose may occur suddenly or insidiously, and symptoms may include confusion, drowsiness, lightheadedness, dizziness, slow or shallow breathing, seizures, loss of muscle tone, loss of consciousness, and coma.
- Other serious adverse events may include: potential development of intrathecal mass formation, drainage, infection, meningitis, unmanageable trunk control, CSF leakage, coma and death.

### COMMON ADVERSE REACTIONS

- The most common adverse reactions in patients with spasticity of spinal origin were hypotonia (25.3%), somnolence (20.9%), dizziness, nausea/vomiting, hypotension, headache, and convulsions.
- The most common adverse reactions in patients with spasticity of cerebral origin were hypotonia (34.7%), somnolence (18.7%), headache (10.7%), agitation, constipation, leukocytosis, chills, and urinary retention.
- Other common adverse events may include hypoventilation, hypertonia, paresthesia, increased salivation, back pain, pruritus, diarrhea, peripheral edema, asthenia, pain, confusion, speech disorder, amblyopia, accidental injury, and dry mouth.

## USE IN SPECIFIC POPULATIONS

- Pregnancy Category C. The effect of baclofen in labor and delivery is unknown.
- Breastfeeding: Baclofen is excreted into breast milk at oral therapeutic doses.
- Pediatric use: Safety and effectiveness in pediatric patients below the age of 4 years have not been established.

**To report suspected adverse reactions, call 888.525.8114, contact the FDA at 800.FDA.1088 or <http://www.fda.gov/medwatch>.**