



**Gablofen®**  
(baclofen injection)

# The Gablofen® Screening Test Dose

FIND OUT IF GABLOFEN® IS RIGHT FOR YOUR PATIENT

**Spasticity affects more than 500,000 people in the United States<sup>1</sup>.  
Are you identifying these patients when they come into your office?**

The 2.25 cc prefilled 50 mcg/mL single packed syringe is designed to allow ease of handling during barbotage. The size offers greater evacuation of cerebrospinal fluid, which yields an increased flow rate into the intrathecal space.<sup>2</sup>

Gablofen® is the only FDA-approved intrathecal Baclofen in convenient prefilled syringes and factory-sealed vials, eliminating the need to draw, measure, dilute, and break glass ampules.<sup>2,3</sup>

For patients found to be responsive to the screening test dose, Gablofen® (baclofen injection) offers 3 refill concentrations – 500, 1,000 and 2,000 mcg/mL – to help optimize Intrathecal Baclofen Therapy™.

See sections 2.2 and 2.3 in the PI for details on the screening trial.



**Start identifying and trialing patients with the  
Gablofen® Screening Test Dose today.**

**Visit [Gablofen.com](http://Gablofen.com) | Call 1.610.974.9760**

1. Stegmayr B, Asplund K. Stroke Incidence and Mortality Correlated to Stroke Risk Factors in the WHO MONICA Project. Stroke [Internet] 1997;28(7):1367–74. Available from: <http://www.citethisforme.com/cite/sources/websitemanualcite>. Accessed: <https://lifewithspasticity.com/definition-and-prevalence>
2. Gablofen [USPI]. Bethlehem, PA: Piramal Critical Care, Inc; March 2017.
3. Orange Book: Approved drug products with therapeutic equivalence evaluations. U.S. Food and Drug Administration [Internet]. 2018 [Cited 16 Aug 2018]; Available from: [https://www.accessdata.fda.gov/scripts/cder/ob/search\\_product.cfm](https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm). Last Accessed April 18, 2018.

## **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.**



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## 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.

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## 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.

**We encourage you to report any adverse events, medical inquiries or product complaints occurring in connection with the use of Gablofen® (baclofen injection) by calling 888.525.8114 or emailing Global Medical Information at [medical.information@piramal.com](mailto:medical.information@piramal.com). You may also report this information to the FDA's MedWatch Reporting System by phone at 1.800.FDA.1088, by facsimile at 1.800.FDA.0178, or by mail using Form 3500 available at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

For additional Important Risk Information, including boxed warning, see enclosed full prescribing information.

