Gablofen®
(baclofen injection)

The Gablofen® Difference

FDA-Approved[1], Convenient Delivery Method[2], Faster Refills & Clinician Support

Intrathecal Baclofen (ITB) Therapy is an established and widely accepted treatment option for severe spasticity.[3] Gablofen® is the only FDA-approved intrathecal Baclofen in prefilled syringes and factory-sealed vials.[1,2]

Gablofen® is indicated for use in the management of severe spasticity of cerebral or spinal origin in patients aged 4 years and above. Gablofen® should be reserved for patients who do not have relief or have side effects they cannot tolerate from taking baclofen orally.[2]

With nearly 20 years in the healthcare industry, Piramal Critical Care is committed to delivering critical care solutions for patients and healthcare providers worldwide.

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.

See Important Risk Information, including boxed warning, on back cover and in enclosed Full Prescribing Information.

Discover what makes Gablofen® different.

CONVENIENT DELIVERY METHOD[2]

An estimated 62%-88% of sharps injuries can be prevented simply by using safer medical devices[4], plus glass particulates and bacterial contamination have long been recognized as hazards associated with ampules[5]. Gablofen® is the only FDA-approved intrathecal Baclofen in convenient prefilled syringes and factory-sealed vials.[1,2] The conveniences of our prefilled syringes and factory-sealed vials include eliminating the need to draw, measure, dilute, and break glass ampules. Fewer steps may enable faster refills and may decrease error. Orders of Gablofen® also qualify for a complimentary Pump Refill Convenience Kit.

FLEXIBLE DOSING OPTIONS

Gablofen® prefilled syringes and factory-sealed vials are available in four concentration choices including 500 mcg/mL, 1000 mcg/mL and 2000 mcg/mL. Additionally, a bolus 50 mcg/mL screening dose is available as a prefilled syringe. With more concentrations available, drug waste is reduced, which may result in overall cost savings. For most patients, it is necessary to increase the dose gradually over time to maintain effectiveness[2], and the 1000 mcg/mL concentration provides a bridge during dose escalation from the 500 mcg/mL dose to the 2000 mcg/mL. This also provides an additional dose option at the time of implantation, which may extend the time needed between refills, which may reduce potential infections associated with such procedures.

CLINICIAN SUPPORT

Piramal enables clinician use accuracy for Gablofen® through comprehensive clinician training, support programs and ongoing education. The on-site support provided increases clinician confidence and comfort related to drug preparation and administration. Piramal's support programs also include speaker programs to provide a platform for Key Opinion Leaders to share best practices, while our roundtables offer a forum for healthcare providers to engage with their peers and find answers to persisting questions.

CUSTOMER SERVICE

Piramal provides each clinician with a multi-tiered team, including an in-house Customer Service Representative, Territory Manager, Area Manager and Key Account Manager. The dedicated team supports their practice's intrathecal spasticity management needs and helps determine the best ways to achieve the practice's goals through ongoing education and collaboration.

For additional Important Risk Information, including boxed warning, see enclosed Full Prescribing Information.

FDA-APPROVED

Gablofen® is a commercially-available and FDA-approved drug, whereas compounded intrathecal baclofen is not.[6] In a study which analyzed 29 ITB samples for the potential clinical impact of compounded versus non-compounded intrathecal baclofen, the only samples with no concentration deviation and consistent drug density were the commercially available, non-compounded products.[6]

COMPATIBILITY

Gablofen® is FDA-approved for use with the Medtronic SynchroMed II Programmable Pump and other pumps labeled for intrathecal administration of Baclofen.[2] By delivering Baclofen directly to the spinal fluid, a more powerful reduction in spasticity may be achieved, with the potential of experiencing fewer systemic side effects.[3]

Gablofen® is reimbursable. Coverage includes Commercial, Medicaid and Medicare.

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. 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.

References

1. 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. Last Accessed April 18, 2018.
2. Piramal Critical Care, Inc. Gablofen® [USPI]. Bethlehem, PA. 2017 [Cited 2018 Aug 16].
3. American Association of Neurological Surgeons (AANS) on Spasticity [Internet]. 2018 [Cited 16 Aug 2018]; Available from: http://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spasticity.
4. Bloodborne Pathogens and Needlestick Prevention [Internet]. 2012 [Cited 16 Aug 2018]; Available from: https://www.osha.gov/SLTC/bloodbornepathogens/evaluation.html
5. L. Painchart, P. Odou, JF Bussieres. Particulate Contamination Associated with the Manipulation of Drugs in Glass Ampules: A Literature Review [Internet]. 2018 [Cited 2018 Aug 15]; Available from: https://www.ncbi.nlm.nih.gov/pubmed/28800916
6. Elizabeth Moberg-Wolff, MD. Potential Clinical Impact of Compounded Versus Noncompounded Intrathecal Baclofen [Internet]. 2009 [Cited 2018 Aug 16]; Available from: https://www.ncbi.nlm.nih.gov/pubmed/19887203

For additional Important Risk Information, including boxed warning, see enclosed Full Prescribing Information.

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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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.

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