

Gablofen[®] (baclofen injection)

Information for patients



Gablofen® (baclofen injection)

Your doctor has prescribed Gablofen for the treatment of your severe spasticity (see enclosed package insert for full prescribing information). Gablofen is the same drug as Lioresal® Intrathecal (baclofen injection), with the same active ingredient, strength, and dosage. Gablofen has been approved by the FDA for use in the Medtronic SynchroMed® II Programmable Pump or other pumps labeled for intrathecal delivery of Gablofen.

High quality you can trust

Gablofen is FDA approved and has met all FDA requirements for safety, quality, and stability. The chemical formulations of Gablofen and Lioresal are exactly the same. Gablofen can be substituted for Lioresal with the full expectation that Gablofen will produce the same clinical effect and safety profile as Lioresal.

Developed by experienced innovators

Gablofen was developed by CNS Therapeutics, a company focused on advancing intrathecal drugs (drugs that are delivered into the space surrounding the spinal cord).

CNS Therapeutics was founded by recognized experts in intrathecal medicine who collaborate with industry experts and innovators to develop high-quality, safe, intrathecal drugs and explore promising new treatments for patients.



Answers to Common Questions

Intrathecal baclofen therapy is not for everyone. Please contact your doctor to find out if it is right for you. A prescription is required.

What is Gablofen?

Gablofen® (baclofen injection) is a drug indicated for the treatment of severe spasticity. (See enclosed package insert for full prescribing information.) Gablofen is the same drug as Lioresal® intrathecal (baclofen injection). Gablofen can be substituted for Lioresal with the full expectation that Gablofen will produce the same clinical effect and safety profile as Lioresal. Gablofen has been approved by the FDA for use in the Medtronic SynchroMed® II Programmable Pump or other pumps labeled for intrathecal delivery of Gablofen.

Intrathecal baclofen injection has been shown to reduce severe spasticity. Results vary and not every individual will receive the same benefits.

The side effects of Gablofen are the same as the side effects of Lioresal. See Safety Information for a list of the most common side effects.

Are Gablofen and Lioresal the same?

Yes. Gablofen is the same drug with the same active ingredient (baclofen), strength, and dosage as Lioresal.

Gablofen and Lioresal are bioequivalent, which means that both products can be interchanged and have the same clinical effect and safety profile when administered as indicated.

Gablofen comes in convenient, ready-to-use vials for pump refills, allowing you to be out of the clinic and on your way.

Who is a candidate for Gablofen?

People who suffer from severe spasticity resulting from cerebral palsy, multiple sclerosis, stroke, traumatic brain injury, or spinal cord injury. Gablofen should be reserved for patients unresponsive to oral baclofen therapy, or those who experience intolerable side effects at effective doses. A screening test will help determine if you will respond to intrathecal medications.

Who is not a candidate for Gablofen?

People who are hypersensitive to oral baclofen should not take Gablofen.

Will Gablofen work with my SynchroMed pump?

Yes, Gablofen has been approved by the FDA for use in the SynchroMed II pump or other pumps labeled for intrathecal delivery of Gablofen.

Gablofen has been rigorously tested and found to be stable in and compatible with the SynchroMed II Pump. Studies of pump performance with Gablofen showed that the pump performed well within the manufacturer's specifications, after six months of testing.

Will my insurance cover Gablofen?

CNS Therapeutics has agreements with both Medicare and Medicaid, and Gablofen is now listed in the major drug databases. Your doctor can use the same reimbursement codes for Gablofen as they used for Lioresal.

Who is CNS Therapeutics?

CNS Therapeutics is a company focused on advancing intrathecal drugs (drugs that are delivered into the space surrounding the spinal cord).

CNS Therapeutics was founded by recognized experts in intrathecal medicine who collaborate with industry experts and innovators to develop high-quality, safe, intrathecal drugs and explore promising new treatments for patients.

Patients are encouraged to report any negative side effects to their healthcare provider. To report suspected adverse reactions, contact CNS Therapeutics Inc. at 1-877-384-0857 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USA Rx only.



Safety Information

The side effects of intrathecal baclofen include sleepiness, dizziness, nausea, headache, convulsions, loose muscles, agitation, constipation, leukocytosis, chills, urinary retention, and low blood pressure. As with most medications, overdose (drug dose is too high) or under dose (drug dose is too low) can occur. Talk with your doctor about the side effects you may experience from your treatment.

Remember to keep your scheduled refill visits so your pump doesn't run out of medication. Sudden withdrawal of Gablofen, regardless of cause, can result in serious complications that include high fever, confusion, muscle stiffness, multiple organ-system failure, and death. Early symptoms of Gablofen withdrawal may include increased spasticity, itching and tingling of extremities. It is very important that your doctor be called right away if you experience any of the above symptoms of baclofen withdrawal.

Although rare, it is possible to receive too much Gablofen. Symptoms of a Gablofen overdose may cause confusion, drowsiness, lightheadedness, dizziness, slow or shallow breathing, seizures, loss of muscle tone, loss of consciousness, and coma. If you experience any of these above symptoms, it is very important that you or your caregiver contact your doctor right away.

Gablofen may cause drowsiness, and you should exercise caution regarding the operation of automobiles or other dangerous machinery, or activities made hazardous by decreased alertness.

Drowsiness associated with Gablofen use can be worsened by alcohol and other CNS depressants. Read all medicine labels carefully, and tell your doctor about all prescription and nonprescription drugs you are using.

If you have more questions, talk with your doctor.

WARNING: DO NOT DISCONTINUE ABRUPTLY

For more safety information, please see full prescribing information.

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 Warnings and Precautions].

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- FDA-approved
- High quality you can trust
- Efficient pump refills
- Developed by experienced innovators

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Lioresal® is a registered trademark of Novartis Pharmaceuticals Corp.
SynchroMed® pump is a registered trademark of Medtronic Inc.

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