Gablofen (baclofen) - Drug Summary

Mallinckrodt Inc. (Brand Pharmaceuticals)

Jump to Section
- BOXED WARNING
- THERAPEUTIC CLASS
- DEA CLASS
- ADULT DOSAGE & INDICATIONS
- PEDIATRIC DOSAGE & INDICATIONS
- ▼ View All Sections...

Related Drug Information ▼

Gablofen (baclofen)

BOXED WARNING

Abrupt discontinuation 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 infusion system, refill scheduling and procedures, and pump alarms. Advise about importance of keeping scheduled refill visits and educate on early symptoms of baclofen withdrawal. Give special attention to patients at apparent risk (eg, spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral/intrathecal therapy).

THERAPEUTIC CLASS

GABA analogue

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Spasticity

Management of Severe Spasticity (eg, of Spinal Cord Origin, Due to Traumatic Brain Injury):

Screening Phase:
Initial: 1mL (50mcg) bolus into intrathecal space by barbotage over ≥1 min

Observe for 4-8 hrs; may administer 2nd bolus of 1.5mL (75mcg) after 24 hrs if initial response is inadequate
Observe for 4-8 hrs; may administer 2mL (100mcg) final bolus 24 hrs after last dose if response is still inadequate
Patients who fail to respond to 100mcg bolus should not receive an implanted pump for chronic infusion

Titration:
Post-Implant Period:
Double the effective screening dose and administer over 24 hrs
If bolus was effective for >8 hrs, starting daily dose should be the screening dose delivered over 24 hrs

Spinal Cord Origin:
After first 24 hrs, slowly increase dose by 10-30% increments q24h until desired effect is achieved

Cerebral Origin:
After first 24 hrs, slowly increase dose by 5-15% q24h until desired effect is achieved

Maint:
Adjust dose during 1st few months while adjusting to lifestyle changes

Spinal Cord Origin:
During pump refills, may increase dose by 10-40% (but not >40%), or reduce dose by 10-20% if experiencing side effects
Range: 12-2003mcg/day
Usual: 300-800mcg/day
Use lowest dose w/ optimal response

Cerebral Origin:
During pump refills, may increase dose by 5-20% (but not >20%), or reduce dose by 10-20% if experiencing side effects
Range: 22-1400mcg/day

Usual: 90-703mcg/day

Consider a "drug holiday" if tolerance develops; refer to PI

PEDIATRIC DOSAGE & INDICATIONS

Spasticity

Management of Severe Spasticity (eg, of Spinal Cord Origin, Due to Traumatic Brain Injury):

≥4 Years:
Screening Phase:
Initial: 1mL (50mcg) bolus into intrathecal space by barbotage over ≥1 min. May 1st try 25mcg in very small patients

Observe for 4-8 hrs; may administer 2nd bolus of 1.5mL (75mcg) after 24 hrs if initial response is inadequate
Observe for 4-8 hrs; may administer 2mL (100mcg) final bolus 24 hrs after last dose if response is still inadequate
Patients who fail to respond to 100mcg bolus should not receive an implanted pump for chronic infusion

Titration:
Post-Implant Period:
Double the effective screening dose and administer over 24 hrs
If bolus was effective for >8 hrs, starting daily dose should be the screening dose delivered over 24 hrs
After the first 24 hrs, slowly increase dose by 5-15% q24h until desired effect is achieved

Maint: Adjust dose during 1st few months while adjusting to lifestyle changes
During pump refills, may increase dose by 5-20% (but not >20%), or reduce dose by 10-20% if experiencing side effects
Range: 22-1400mcg/day
Usual: 90-703mcg/day

<12 Years:
Range: 24-1199mcg/day
Usual: 274mcg/day
Use lowest dose w/ optimal response

Consider a "drug holiday" if tolerance develops; refer to PI

ADMINISTRATION

Intrathecal route

Only for use w/ Medtronic SynchroMed II Programmable Pump or other pumps labeled for intrathecal administration of baclofen
Refer to manufacturer's manual for specific instructions and precautions for programming the pump and/or refilling the reservoir

Preparation
Screening:
Use 1mL screening syringe only (50mcg/mL) for bolus inj into subarachnoid space
For a 50mcg bolus dose, use 1mL of screening syringe
Use 1.5mL of 50mcg/mL baclofen inj for a 75mcg bolus dose
For max screening dose of 100mcg, use 2mL of 50mcg/mL baclofen inj (2 screening syringes)

Maint:
Specific concentration that should be used depends upon total daily dose required as well as delivery rate of pump
For patients who require concentrations other than 500mcg/mL, 1000mcg/mL or 2000mcg/mL, baclofen must be diluted w/ sterile preservative-free NaCl for inj

Delivery Regimen
Intrathecal baclofen is most often administered in a continuous infusion mode immediately following implant
For those patients implanted w/ programmable pumps and who have achieved relatively satisfactory control on continuous infusion, further benefit may be attained using more complex schedules of baclofen delivery
Changes in flow rate should be programmed to start 2 hrs before time of desired clinical effect

HOW SUPPLIED

Inj: 50mcg/mL [1mL], 500mcg/mL [20mL], 1000mcg/mL [20mL], 2000mcg/mL [20mL]

CONTRAINDICATIONS

IV, IM, SQ, or epidural administration.

WARNINGS/PRECAUTIONS

Use extreme caution when filling the Medtronic SynchroMed II Programmable Pump equipped w/ inj port that allows direct access to the intrathecal catheter; direct inj into catheter through the catheter access port may cause a life-threatening overdose. Potential for contamination due to nonsterile external surface of prefilled syringe. Use of prefilled syringe in an aseptic setting (eg, operating room) to fill sterile intrathecal pumps prior to administration in patients is not recommended, unless the external surface of the prefilled syringe is treated to ensure sterility. Potentially life-threatening CNS depression, cardiovascular (CV) collapse, and/or respiratory failure may occur; physicians must be adequately trained and educated in chronic intrathecal infusion therapy. Do not implant pump until response to bolus inj is evaluated. Resuscitative equipment should be available. Monitor closely during initial phases of pump use and when dosing rate or concentration is adjusted until response is acceptable and stable. Monitor for signs of overdose (eg, drowsiness, lightheadedness, respiratory depression, seizures, loss of consciousness, coma). Potential risk for withdrawal syndrome; avoid abrupt discontinuation. Seizures reported during overdose and w/ withdrawal from intrathecal therapy, as well as in patients maintained on therapeutic doses. Caution w/ psychotic disorders, schizophrenia, or confusional states; exacerbation of these conditions may occur. Caution w/ history of autonomic dysreflexia. Patients should be infection-free prior to screening trial and pump implantation. A sudden need for substantial dose escalation may indicate catheter complication. Caution w/ dose titration when spasticity is necessary to sustain upright posture

and balance in locomotion. Titrate dose to maintain some degree of muscle tone, and allow occasional spasms to help support circulatory function, prevent DVT formation, and optimize daily living activities. Drowsiness reported. May impair mental/physical abilities. Cases of intrathecal mass at the tip of the implanted catheter reported; carefully monitor for any new neurological signs or symptoms. Ovarian cysts reported w/ oral therapy. Children should be of sufficient body mass to accommodate implantable pump for chronic infusion.

ADVERSE REACTIONS

Somnolence, dizziness, N/V, hypotension, headache, convulsions, hypotonia, agitation, constipation, leukocytosis, chills, urinary retention.

DRUG INTERACTIONS

D/C oral antispasticity medication to avoid possible overdose or adverse drug interactions; avoid abrupt reduction or discontinuation of concomitant antispasmodics. Additive CNS depressant effect w/ alcohol and other CNS depressants. Hypotension and dyspnea reported w/ epidural morphine.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

GABA analogue; has not been established. Inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from primary afferent terminals. May exert effects by stimulating $GABA_B$ receptor subtype.

PHARMACOKINETICS

Distribution: (Oral) Found in breast milk. **Elimination:** $T_{1/2}$ (CSF)=1.51 hrs (over the first 4 hrs).

ASSESSMENT

Assess for drug hypersensitivity, spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral/intrathecal therapy, origin of spasticity, presence of infection, psychotic disorders, schizophrenia, confusional states, history of autonomic dysreflexia, pregnancy/nursing status, and for possible drug interactions. Assess body mass in children.

MONITORING

Monitor for signs of overdose; withdrawal symptoms; drowsiness; exacerbations of psychotic disorders, schizophrenia or confusional states; CNS depression; CV collapse; respiratory failure; intrathecal mass formation; new neurological signs/symptoms; catheter complications; and other adverse reactions. Monitor response to therapy.

PATIENT COUNSELING

Inform patients and caregivers on the risks of mode of treatment. Educate patient and caregivers on the signs/symptoms of overdose and withdrawal, procedures to follow in the event of overdose or withdrawal, and on proper home care of pump and insertion site. Explain the importance of keeping scheduled refill visits. Advise that drug may cause drowsiness; instruct to exercise caution when operating automobiles or other dangerous machinery, or activities made hazardous by decreased alertness. Inform that the drowsiness associated w/ the drugs use can be worsened by alcohol and other CNS depressants. Advise to inform physician about all prescription and nonprescription drugs concurrently being taken.

STORAGE

≤30°C (86°F). Refrigeration not required. Do not freeze. Do not heat sterilize. Do not autoclave.

Back to top