Baclofen

Brand names	Lioresal IT (intrathecal)
Medication error potential	High-alert medication associated with significant patient harm should an error occur.[1] Look-alike, sound-alike drug names. Baclofen may be confused with bethanechol, Blocadren, and Batroban.[2] Lioresal may be confused with Lotensin and lisinopril.[2]
Contraindications and warnings	*Not for IV, IM, sub-Q, or epidural administration.* Should not be given if known hypersensitivity to baclofen or any components of the formulation.[3] **U.S. boxed warning:** Abrupt withdrawal has caused severe sequelae including high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity.[3] In rare cases, rhabdomyolysis, multiple organ system failure, and death has occurred.[3] (See the Comments section.) **Other warnings:** Should not be used for spasticity to maintain posture or balance.[3]
Infusion-related cautions	*Not for IV, IM, sub-Q, or epidural administration. Should only be used in an FDA-approved implantable pump.* Abrupt discontinuation/withdrawal of therapy may cause high fever, altered mental status, exaggerated rebound spaciticity and muscle rigidity. Occassionaly rhabdomyolysis, multisystem organ failure, and death have occurred. (See Significant Adverse Effects in the Comments section.)[3] A sudden requirement for substantial dose escalation may indicate catheter complication (i.e., dislodgement).[3-6] Use extreme caution in filling implantable pump that allows direct access to the intrathecal (IT) catheter as direct injection through the catheter access port may cause a life-threatening overdose.[3]
Dosage	**IT administration (*not intended for IV administration*)** **Severe spasticity (spinal cord or cerebral origin)** Due to the nature of administration and need for pump implantation, usually a minimum patient weight of 15 kg is necessary.[7] **Test dose:** 50-mcg test dose into IT space via barbotage over ≥1 minute.[3-6,8-15] Use 25-mcg test dose in very small children.[3,14] If insufficient response within 4–8 hours, a second 75-mcg test dose can be given 24 hours after initial test dose.[3,8,10,12,14] If response continues to be inadequate, a third 100-mcg test dose[3,14,16] may be given 24 hours after the second test dose.[3,8] If an inadequate response continues, the patient is not a candidate for chronic IT baclofen therapy.[3] A significant decrease in muscle tone and/or frequency and/or severity of spasms is considered a positive response.[3] Patients with spasticity due to traumatic brain injury should not be evaluated for long-term IT baclofen until at least 1 year after the injury.[3] **Maintenance therapy:** Initial daily dose is based on the effective test dose and duration of its effects.[17] If the test dose response lasted ≤8 hours, the initial daily dose should be twice the test dose.[3,14] If the response lasted >8 hours, the initial daily dose should equal the test dose.[3,14] The dose should be increased every 24 hours by 5% to 15% until desired results are achieved.[3] The infusion rate (mcg/hr) is the total daily dose divided by 24 hours except when complex dosing is used.[3] (See the Continuous Infusion section.) **≤12 years:** 100–300 mcg/day (4.2–12.5 mcg/hr). Average dose of 274 mcg/day.[3] Doses as large as 1000–1500 mcg/day have been used.[3,12] **>12 years:** 300–800 mcg/day (12.5–33.3 mcg/hr).[3,13] Doses as large as 2000 mcg/day have been used in *adults*, but information on doses larger than 1000 mcg/day is limited.[3,18]

Dosage *(cont.)*	If spasticity is of cerebral origin doses as large as 1000 mcg/day have been used.[3,10,17] Doses up to 1400 mcg/day have been given to children.[10,18] **Neuroleptic malignant syndrome (NMS):** IT baclofen has been used successfully to treat NMS in *adults* and one pediatric patient.[22] **Status dystonicus:** IT baclofen has been used for this disorder, but reports are limited and results have been conflicting.[50] **Tetanus:** IT baclofen has also been used successfully in treating muscle rigidity associated with tetanus in *adults*.[18-21]
Dosage adjustment in organ dysfunction	Baclofen is primarily eliminated unchanged by the kidneys (>70%). Patients with renal impairment may require smaller doses.
Maximum dosage	Although doses up to 1500–2000 mcg/day have been given,[12] there is limited experience with dosages >1000 mcg/day.[3]
Additives	9 mg/mL (0.39 mEq/mL)[3,23]
Suitable diluents	Sterile, preservative-free NS for injection[3,23]
Maximum concentration	50 mcg/mL (commercially available) for test dose. For maintenance dosing the commercially available strengths *must* be diluted if the patient requires strengths other than 0.5 mg/mL or 2 mg/mL.[3] IT refill kit concentration 0.5 mg/mL in 20-mL ampules or 2 mg/mL in 5-mL or 20-mL ampules.[3]
Preparation and delivery	*Parenteral products should be visually inspected for particulate matter and discoloration before use. Refer to appropriate references for more information on compatibility with other drugs and solutions; compatibility following Y-site delivery, and suggested storage and extended stability.*[23] **Delivery system issues:** Catheter complication may cause a sudden requirement for a substantial increase or decrease in dose.[3-6] Pump malfunction can also potentially lead to an overdose.[24] **Stability:** Because the product is preservative free, each vial is intended for single use only and any unused solution should be discarded. It does not require refrigeration and is stable at 37°C; however, storage temperature should not exceed 30°C, and it should not be frozen or heat sterilized.[3,23] Appears to be stable in an implantable pump with morphine sulfate or clonidine without significant loss of either drug; however, <4% loss of morphine concentration occurred during a 30-day infusion course.[23]
IV push	Not intended for IV administration[3]
Intermittent infusion	Not applicable
Continuous infusion	Administered *intrathecally* via implantable pump device. Total daily dose in mcg divided by 24 hours = infusion rate.[3] Do not discontinue abruptly.[3] (See U.S. boxed warning in the Contraindications and Warnings section and see the Comments section.) A complex (flex) dosing schedule has been described in the literature in both children and *adults* to allow for dosing *intrathecally* at varying rates to correspond with variation in muscle tone that occurs in a typical day (i.e., nighttime spasms in multiple sclerosis, etc.).[25,26]
Other routes of administration	Not intended for IM, IV, sub-Q, or epidural administration.[3] *Intraventricular* administration has been reported as an alternative for patients with dystonia; may not be effective for spasticity.[27,28]