



Medtronic

INDICATIONS, DRUG STABILITY, AND EMERGENCY PROCEDURES

SynchroMed® and IsoMed® implantable infusion systems

Reference manual

Rx only

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Narcan® is a registered trademark of DuPont.

Lioresal® is a registered trademark of Novartis Pharma, AG.

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Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, and component disposal.

Refer to the device implant manual for device description, package contents, device specifications, and instructions for use.

Indications

Physicians prescribing the SynchroMed II, SynchroMed, or SynchroMed EL Infusion Systems or the IsoMed Constant-Flow Infusion System for use with the drugs listed in Table 1 must be familiar with the indications, contraindications, warnings, precautions, adverse events, dosage and administration information, and screening procedures described in the drug labeling. Each system includes (at a minimum) a pump and a catheter.

Warning: Nonindicated formulations (including drugs not listed in Table 1, admixtures, compounded drugs, and unapproved drug concentrations) are not approved for use or tested with the infusion system. Use of nonindicated drugs or fluids can result in increased risks to the patient, damage to the infusion system requiring surgical replacement, and a loss or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose.

Table 1. Drug indications for Medtronic implantable infusion systems.

Drugs approved for use with infusion system ^a	SynchroMed II	SynchroMed and SynchroMed EL	IsoMed
The chronic epidural/intrathecal infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain. The maximum approved concentration is 25 mg/mL. A 0.9% solution of preservative-free sodium chloride injection, USP, can be used to achieve the physician-prescribed concentration of preservative-free morphine sulfate sterile solution.	X	X	X ^b
The chronic intravascular infusion of floxuridine (FUDR) for the treatment of primary or metastatic cancer. Bacteriostatic water or preservative-free sterile saline (USP) can be used to achieve the physician prescribed concentration of chemotherapy drugs or to flush the pump reservoir. Saline or heparinized physiological saline (unless contraindicated) may be used during an interruption in chemotherapy to maintain pump and catheter patency.	X	X	X

Table 1. Drug indications for Medtronic implantable infusion systems.

Drugs approved for use with infusion system^a	SynchroMed II	SynchroMed and SynchroMed EL	IsoMed
The chronic intravascular infusion of methotrexate for the treatment of primary or metastatic cancer. Bacteriostatic water or preservative-free sterile saline (USP) can be used to achieve the physician prescribed concentration of chemotherapy drugs or to flush the pump reservoir. Saline or heparinized physiological saline (unless contraindicated) may be used during an interruption in chemotherapy to maintain pump and catheter patency.	X	X	—
The chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain. The maximum approved concentration is 100 µg/mL. A 0.9% solution of preservative-free sodium chloride injection, USP, can only be used with preservative-free ziconotide sterile solution after the initial fill of the pump with this drug.	X	X	—
The chronic intrathecal infusion of Lioresal Intrathecal (baclofen injection) in the management of severe spasticity. The maximum approved concentration is 2 mg/mL. A 0.9% solution of preservative-free sodium chloride injection, USP, can be used to achieve the physician-prescribed concentration of Lioresal Intrathecal (baclofen injection).	X	X	—

Table 1. Drug indications for Medtronic implantable infusion systems.

Drugs approved for use with infusion system^a	SynchroMed II	SynchroMed and SynchroMed EL	IsoMed
The chronic intravascular infusion of doxorubicin or cisplatin for the treatment of primary or metastatic cancer. Bacteriostatic water or preservative-free sterile saline (USP) can be used to achieve the physician prescribed concentration of chemotherapy drugs or to flush the pump reservoir. Saline or heparinized physiological saline (unless contraindicated) may be used during an interruption in chemotherapy to maintain pump and catheter patency.	—	X	—
The intravenous infusion of clindamycin for the treatment of osteomyelitis.	—	X	—

^a Refer to the appropriate drug labeling for a complete list of indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.

^b IsoMed is approved only for intrathecal infusion of preservative-free morphine sulfate sterile solution.

X Specific pump is approved for use with drug.

— Specific pump is not approved for use with drug.

Drug stability

Testing has indicated that the drugs in Table 2 are stable and compatible with the infusion systems listed in the table. Refer to the appropriate drug labeling for complete prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

Table 2. Stability^a of drugs approved for use with Medtronic implantable infusion systems.

	SynchroMed II		SynchroMed and SynchroMed EL		IsoMed
	Initial fill ^b	Refill	Initial fill ^b	Refill	
Cisplatin (1 mg/mL)	—		7 days		—
Clindamycin (70 mg/mL)	—		28 days		—
Doxorubicin (5 mg/mL)	—		14 days		—
Floxuridine (FUDR) (20 mg/mL)	56 days		28 days		27 days
Lioresal Intrathecal (baclofen injection) (0.5 mg/mL) (2 mg/mL)	180 days		90 days		—
Methotrexate (5 mg/mL)	56 days		28 days		—
Morphine sulfate sterile solution (preservative-free) (25 mg/mL)	180 days		90 days		90 days
Ziconotide sterile solution (preservative-free)	Initial fill^b	Refill	Initial fill^b	Refill	—
25 µg/mL, undiluted	14 days	60 days	14 days	60 days	—
100 µg/mL, undiluted	*	60 days	*	60 days	—
100 µg/mL, diluted	*	40 days	*	40 days	—

^a Stability is defined as 90% of initial concentration.

^b For a pump that has not been previously filled with preservative-free ziconotide sterile solution, only the undiluted 25 µg/mL formulation of preservative-free ziconotide sterile solution can be used for the initial pump fill. Refill of the pump with this drug should be completed within 14 days to avoid underdosing the patient. At initial fill of a new pump, some of the drug is lost due to two factors that do not occur upon subsequent refills: adsorption on internal device surfaces, such as titanium, and by dilution in the residual space of the device. Refer to the drug labeling for additional information.

— Drug is not approved for use with this specific pump.

* Formulation is not applicable for the initial pump fill.

Emergency procedures

Morphine intrathecal/epidural overdose

Consult the patient's medical record or with the patient's physician to confirm the drug or drug concentration within the pump reservoir.

Symptoms

Respiratory depression with or without concomitant central nervous system depression (ie, dizziness, sedation, euphoria, anxiety, seizures, respiratory arrest).

Actions

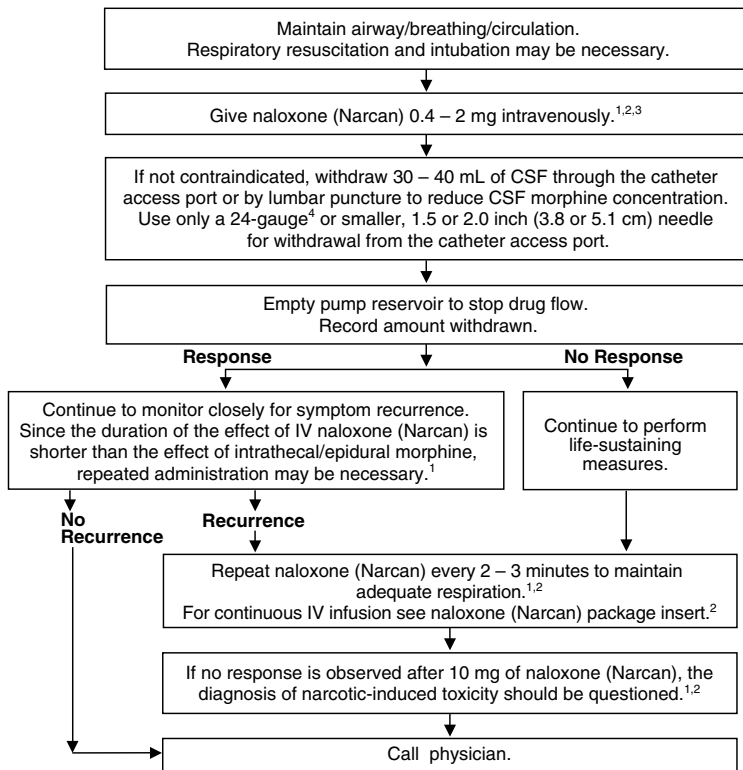


Figure 1. Morphine intrathecal/epidural overdose emergency procedures.

- 1 Infumorph (Preservative-free morphine sulfate sterile solution) manufacturer's package insert (Baxter Healthcare Corporation).
- 2 Narcan (naloxone hydrochloride) manufacturer's package insert (DuPont).
- 3 Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
- 4 Use a 25-gauge needle for withdrawal from a SynchroMed or SynchroMed EL catheter access port. Use a 24- or 25-gauge needle for withdrawal from a SynchroMed II or IsoMed catheter access port.

Lioresal Intrathecal (baclofen injection) overdose

Consult the patient's medical record or with the patient's physician to confirm the drug or drug concentration within the pump reservoir.

Symptoms

Drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia, and loss of consciousness progressing to coma.

There is no specific antidote for treating overdoses of Lioresal Intrathecal (baclofen injection). However, anecdotal reports suggest that intravenous physostigmine may reverse central side effects, notably drowsiness and respiratory depression.

Actions

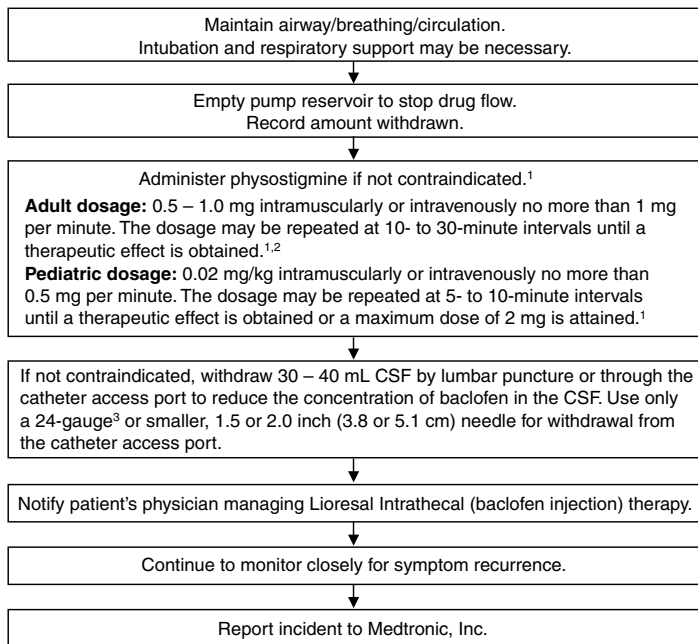


Figure 2. Lioresal Intrathecal (baclofen injection) overdose emergency procedures.

- 1 Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
- 2 Müller-Schwefe G, Penn RD. Physostigmine in the treatment of intrathecal baclofen overdose: report of three cases. *J Neurosurg.* August 1989;71:273-275.
- 3 Use a 25-gauge needle for withdrawal from a SynchroMed or SynchroMed EL catheter access port. Use a 24- or 25-gauge needle for withdrawal from a SynchroMed II or IsoMed catheter access port.

Lioresal Intrathecal (baclofen injection) underdose/withdrawal

Consult the patient's medical record or with the patient's physician to confirm the drug or drug concentration within the pump reservoir.

Symptoms of underdose

Pruritus without rash, hypotension, paresthesia, fever, and altered mental state.

Symptoms of withdrawal

Exaggerated rebound spasticity and muscle rigidity, rhabdomyolysis, and multiple organ failure. The condition may resemble autonomic dysreflexia, sepsis, malignant hyperthermia, and neuroleptic-malignant syndrome.

Actions

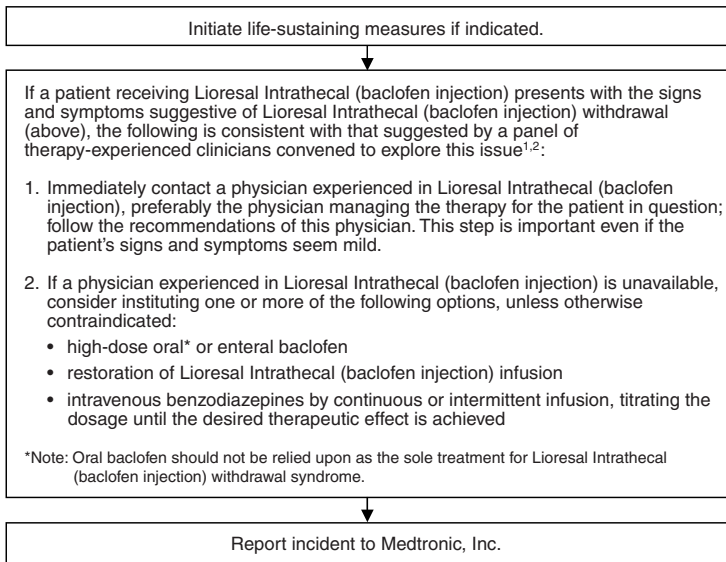


Figure 3. Lioresal Intrathecal (baclofen injection) underdose/withdrawal emergency procedures.

- 1 Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
- 2 Coffey RJ, Edgar TS, Francisco GE, et al. Abrupt withdrawal from intrathecal baclofen: recognition and management of a potentially life-threatening syndrome. *Arch Phys Med Rehabil.* 2002;83:735-741.

Emergency procedure to empty the pump reservoir

Equipment

- 22-gauge needle
 - 20-mL syringe(s)
 - 3-way stopcock
 - Antiseptic agent
1. Locate the pump by palpation. The reservoir fill port is located in the CENTER of the pump.
 2. Prepare the injection site by cleansing the area using antiseptic agent.
 3. Gently insert the 22-gauge needle into the center of the reservoir fill port septum until the needle touches the needle stop. If the clinician encounters resistance during needle insertion, the clinician should reassess placement. Do not force the needle. Hitting metal or the feel of abnormal resistance during the procedure may be an indication that the needle is not in the center of the reservoir fill port septum.



Cautions:

- The IsoMed pump reservoir contents are under significant pressure. To prevent the reservoir contents from being ejected, do not use an open syringe when emptying the pump.
 - When removing a vesicant or cytotoxic drug, care must be taken to prevent spillage or leakage of the drug into adjacent tissue.
4. If desired, use a 3-way stopcock. Withdraw fluid from the pump reservoir using passive backflow and gentle negative pressure. Empty the pump reservoir until back-flow has stopped and wait five seconds to ensure all fluid is removed and the pump reservoir is empty. Depending on pump reservoir volume, more than one syringe may be needed to empty the pump.
 5. Remove the needle from the reservoir fill port.
 6. Record in the patient chart the amount of fluid emptied from the pump reservoir.

Technical Services

For additional information, contact Medtronic Technical Services at 1-800-328-0810.



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