Medtronic

Emergency procedure for baclofen injection overdose

Disclaimer: This document is for the attention of healthcare professionals only. These actions should only be taken by someone who is a healthcare professional.

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

Symptoms:

Drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, hypothermia, seizures, rostral progression of hypotonia, and loss of consciousness progressing to coma. There is no specific antidote for treating overdoses of intrathecal baclofen injection.

Actions:

Maintain airway/ breathing/circulation. Intubation and respiratory support may be necessary.

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Empty pump reservoir to stop drug flow. Record amount withdrawn.

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For intrathecal overdose:

If not contraindicated, withdraw 30–40 mL CSF by lumbar puncture, or through the catheter access port, to reduce the concentration of baclofen in the CSF. Use only a 24-gauge or smaller 1.5 or 2.0 inch (3.8 or 5.1 cm) needle for withdrawal from the catheter access port.[1]

For subcutaneous overdose (e.g. pocket fill):

Proceed immediately to the next step.

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Notify patient's physician managing baclofen injection therapy.

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Continue to monitor closely for symptom recurrence.

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Report incident to Medtronic, Inc.

Figure 1. Intrathecal baclofen injection overdose emergency procedures.

Emergency procedure to empty the pump reservoir

Equipment: • 22-gauge non-coring needle • 20 mL syringe(s) • 3-way stopcock or extension set with clamp • Antiseptic agent

1. Assemble the needle, syringe, and stopcock or extension set.
2. Locate the pump by palpation. The reservoir fill port is located in the CENTRE of the pump. If you have difficulty identifying the pump features, you may seek assistance from another clinician. If deemed necessary by the clinician, x-ray and fluoroscopy can be used to assist in locating or determining the orientation of the pump.
3. Prepare the injection site by cleansing the area using an antiseptic agent.
4. Gently insert the 22-gauge non-coring needle into the centre of the reservoir fill port until the needle touches the bottom of the reservoir fill port (Figure 2).
   During proper needle insertion, the needle will:
   - Pass through the patient's skin and subcutaneous tissue
   - Hit the silicone septum (scar tissue, if present, can feel similar to the septum)
   - Pass through the septum, and
   - Hit the metal bottom of the reservoir fill port. (the top of the pump is metal and hitting the top of the pump can feel similar to hitting the bottom of the reservoir fill port)

   If excessive resistance is encountered during needle insertion, reassess placement. Do not force the needle. The feel of abnormal resistance during the procedure may be an indication that the needle is not in the centre of the reservoir fill port.
5. Open the clamp or stopcock and slowly withdraw the fluid from the reservoir into the empty syringe.
6. Depending on pump reservoir volume, more than one syringe may be needed to empty the pump. Close the clamp or stopcock when changing syringes.
7. Completely empty the pump. When the pump is empty, the bubbles will stop forming, and negative pressure in the syringe can be felt.
8. Remove the needle from the reservoir fill port.
9. Record in patient chart the amount of fluid emptied from the pump reservoir.

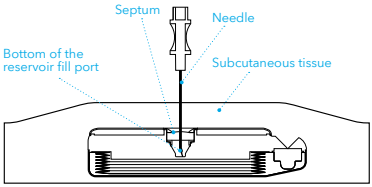


Figure 2. View inside of a SynchroMed™ programmable pump while the needle is fully and properly inserted.

Emergency procedure for baclofen injection underdose/withdrawal

Disclaimer: This document is for the attention of healthcare professionals only. These actions should only be taken by someone who is a healthcare professional.

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

Symptoms of underdose:

Pruritus without rash, hypotension, paraesthesia, fever, and altered mental state. Priapism may develop or recur if treatment with intrathecal baclofen is interrupted.

Symptoms of withdrawal:

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

Actions:

Initiate life-sustaining measures if indicated.

Report incident to Medtronic, Inc.

If a patient receiving intrathecal baclofen injection presents with the signs and symptoms suggestive of withdrawal (above), the following is consistent with that suggested by a panel of therapy-experienced clinicians convened to explore this issue[2,3]:

1 Immediately contact a physician experienced in intrathecal baclofen injection (preferably the physician managing the therapy for the patient in question). Follow the recommendations of this physician.

2 If a physician experienced in intrathecal baclofen injection is unavailable, consider instituting one or more of the following options, unless otherwise contraindicated:

- High-dose oral* or enteral baclofen
- Restoration of intrathecal baclofen injection infusion with intravenous benzodiazepines by continuous or intermittent infusion, titrating the dosage until the desired therapeutic effect is achieved

*Note: Oral baclofen should not be relied upon as the sole treatment for intrathecal baclofen injection withdrawal syndrome.

Figure 3. Intrathecal baclofen injection underdose/withdrawal emergency procedures.

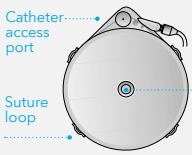
1. Use a 24- or 25-gauge needle for withdrawal from a SynchroMed™ II catheter access port.
2. Refer to the drug manufacturer's package insert for a complete list of indications, contraindications, warnings, precautions, adverse events, and dosage and administration information.
3. Coffey RJ, Edgar TS, 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.

If you have any questions specific to the medicinal product that you are using this device to administer, please contact the Marketing Authorisation Holder. When ITB is mentioned, we are considering Intrathecal baclofen (an anti-spastic) administered by an intrathecal drug delivery pump therapy. Medtronic provides only the intrathecal drug delivery pump and the catheter; the intrathecal baclofen is provided by an external company.

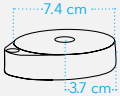
Medtronic SynchroMed™ pump descriptions

Pump name	Model	Catheter access port?	Reservoir size
SynchroMed™ II	8637-40	Yes, funnel-shaped	40 mL
SynchroMed™ II	8637-20	Yes, funnel-shaped	20 mL

SynchroMed™ II pumps



Pump dimensions



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