



Medtronic

Morphine Patient Education

PATIENT QUESTION AND ANSWER

Targeted drug delivery therapy uses an implanted pump to deliver pain medication into the fluid-filled space surrounding the spinal cord (intrathecal space). Some doctors choose to use morphine in this system. There are known risks associated with the use of morphine medications, such as overdose. If you receive too much morphine in combination with oral medications or patches, you can develop serious breathing problems. In rare cases, death has occurred. This information will help you understand the risks of morphine overdose.

It is important that you discuss the medication that will be used in your Medtronic drug delivery system with your doctor before you begin receiving the therapy and at regular refill appointments. Read the important information below with the understanding that it does not take the place of discussions with your doctor.

What are the signs of a morphine overdose?

Signs of morphine overdose include:

- Lightheadedness and dizziness, progressing to extreme drowsiness and sleepiness
- Excitability, anxiety
- Very slow and shallow breathing (less than 8-10 breaths per minute)
- Unconsciousness or inability to awaken

Advise your friends and family to call 911 immediately for emergency help if you exhibit any of these symptoms. Overdose is a serious, life-threatening condition that requires emergency care.

When is a morphine overdose most likely to occur?

When using morphine in your implanted drug delivery system, overdose is most likely to occur after:

- the first dose of morphine is delivered through your pump.
- your pump is refilled.
- your pump and/or catheter is surgically repaired or replaced.

When your pump is implanted, you will be under close medical supervision for at least 24 hours and up to several days after your first dose of medication. You also may be under medical supervision when your pump and/or catheter is refilled, surgically repaired, or replaced.

It is important that your physician know if you are taking any other oral medications, including oral opioids, in addition to the morphine that you receive through the drug delivery system. Take supplemental medications, including oral opioids or pain patches, as directed by your doctor. Some other oral medications, such as medications that relieve anxiety or improve sleep, may also cause breathing problems, so it is important to tell your doctor about all medications that you are taking.

Besides getting too much medication, are there other factors that may put me at greater risk when using morphine?

Some health conditions may increase your risk of serious or life-threatening medical problems—including death—when using morphine in your pump.

Tell your doctor if you suffer from:

- Kidney or liver disease
- Lung diseases (e.g., asthma, chronic obstructive pulmonary disease [COPD])
- Breathing problems (e.g., slow or shallow breathing, sleep apnea)

What is the relationship between morphine and breathing problems?

Morphine can affect breathing. It is important that everyone in your household knows that you have morphine in your pump, and to call 911 immediately if you ever show any of the following danger signs:

- Snoring heavily and cannot be awakened
- Having trouble breathing
- Exhibiting extreme drowsiness and slow breathing
- Having slow, shallow breathing with little chest movement
- Having a faster or slowed heartbeat
- Feeling faint, very dizzy, confused, or experiencing heart palpitations

How can I use opioids as safely as possible?

Pain SAFE, a program sponsored by the National Pain Foundation to improve the safety of patients receiving oral opioids, offers Six Steps to Safety when taking any opioid pain medication:

1. Never take a prescription painkiller unless it is prescribed to you.
2. Do not take pain medicine with alcohol.
3. Do not take more doses than prescribed.
4. Understand that use of other sedative or anti-anxiety medications can be dangerous because it increases the toxicity of the pain medication.
5. Avoid using prescription painkillers to fall to sleep.
6. Lock up prescription opioids in your home to protect your children, family, and the public from misuse.

In addition to these steps, do not take any other medicine while using opioid pain medication until you have talked with your doctor.

Also, make sure your doctor and pharmacist know all the medicines you are taking, including prescription and nonprescription medicines, vitamins, and herbal supplements.

SynchroMed® II Drug Infusion System Brief Summary:

Medtronic DBS Parkinson's Control Therapy and Tremor Control Therapy: Patients should always discuss the potential risks and benefits with a physician.

Indications: US: Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity; chronic intravascular infusion of floxuridine (FUDR) or methotrexate for the treatment of primary or metastatic cancer. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

Contraindications: Infection; implant depth greater than 2.5 cm below skin; insufficient body size; spinal anomalies; drugs with preservatives, drug contraindications, drug formulations with pH ≤3, use of catheter access port (CAP) kit for refills or of refill kit for catheter access, blood sampling through CAP in vascular applications, use of Personal Therapy Manager to administer opioid to opioid-naïve patients or to administer ziconotide.

Warnings: Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose. Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, screening procedures and underdose and overdose symptoms and methods of management. Physicians must be familiar with the drug stability information in the product technical manuals and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion. Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system. An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients on intraspinal therapy carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation.

Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention, including prodromal signs and symptoms of inflammatory mass. Failure to recognize signs and symptoms and seek appropriate medical intervention can result in serious injury or death. Instruct patients to notify their healthcare professionals of the implanted pump before medical tests/procedures, to return for refills at prescribed times, to carry their Medtronic device identification card, to avoid manipulating the pump through the skin, to consult with their clinician if the pump alarms and before traveling or engaging in activities that can stress the infusion system or involve pressure or temperature changes. Strong sources of electromagnetic interference (EMI), such as short wave (RF) diathermy and MRI, can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. Avoid using shortwave (RF) diathermy within 30 cm of the pump or catheter. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. Drug infusion is suspended during MRI; for patients who can not safely tolerate suspension, use alternative drug delivery method during MRI. Patients receiving intrathecal baclofen therapy are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively. Confirm pump status before and after MRI. Reference product labeling for information on sources of EMI, effects on patient and system, and steps to reduce risks from EMI.

Precautions: Monitor patients after device or catheter replacement for signs of underdose/overdose. Infuse preservative-free (intraspinal) saline or, for vascular applications, infuse heparinized solutions therapy at minimum flow rate if therapy is discontinued for an extended period of time to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions. EMI from the SynchroMed programmer may interfere with other active implanted devices (e.g., pacemaker, defibrillator, neurostimulator).

Adverse Events: Include, but are not limited to, spinal/vascular procedure risks; infection; bleeding; tissue damage, damage to the system or loss of, or change in, therapy that may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose, due to end of device service life, failure of the catheter, pump or other system component, pump inversion, technical/programming errors, or improper use, including use of non-indicated formulations and/or not using drugs or system in accordance with labeling; pocket seroma, hematoma, erosion, infection; post-lumbar puncture (spinal headache); CSF leak and rare central nervous system pressure-related problems; hygroma; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; potential serious adverse effects from catheter fragments in intrathecal space, including potential to compromise antibiotic effectiveness for CSF infection; anesthesia complications; body rejection phenomena; local and systemic drug toxicity and related side effects; potential serious adverse effects from catheter placement in intravascular applications.

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