

Summary of Approved Drugs

SynchroMed® II Infusion System

For complete information, refer to the *Indications, Drug Stability, and Emergency Procedures* reference manual, product labeling number (MA12510A013)

Physicians prescribing the SynchroMed II Infusion System for use with the drugs listed below 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 below, 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.

Drugs for which the SynchroMed II Infusion System is approved

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(Reference MA12510A013)

The chronic epidural/intrathecal infusion of preservative-free morphine sulfate (or morphine hydrochloride) 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 can be used to achieve the physician-prescribed concentration of preservative-free morphine sulfate (or morphine hydrochloride) sterile solution.

The chronic intrathecal infusion of 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 can be used to achieve the physician-prescribed concentration of Lioresal Intrathecal (baclofen injection).

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 can only be used with preservative-free ziconotide sterile solution after the initial fill of the pump with this drug.

The chronic intravascular infusion of floxuridine (FUDR) for the treatment of primary or metastatic cancer.

- Bacteriostatic water or preservative-free sterile saline 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.

The chronic intravascular infusion of methotrexate for the treatment of primary or metastatic cancer.

- Bacteriostatic water or preservative-free sterile saline 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.
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