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Baptist Health Case Study

Reducing Waste with Ready-to-Administer Prefilled Syringes: A Health-System Implementation

79%
Reduction in overall Hydromorphone HCl waste events*

42%
Reduction in overall Fentanyl Citrate waste events*

THE CHALLENGES

- Lack of dosage form standardization for IV push opioids
- Inefficient clinician workflows related to dispensing and wasting controlled substances

THE SOLUTION

- Use Simplist MicroVault® ready-to-administer prefilled syringes to more closely match clinical practice for commonly used IV push opioids
- Utilize Simplist MicroVault Cassettes in Omnicell's Controlled Substance Dispenser to reduce countbacks of new prefilled syringes

THE IMPACT

- Decreased hydromorphone and fentanyl waste by 79% and 42%, respectively, resulting in fewer opportunities for diversion*
- Simplified the IV push workflow with fentanyl citrate, hydromorphone HCl, and morphine sulfate in secure packaging
- Reduced time nurses spend counting and wasting controlled substances

***Data provided by Baptist Health Floyd and analyzed by Fresenius Kabi's Simplist Support Team.*

Introduction

Baptist Health is a full-spectrum health system dedicated to improving the health of its communities. Founded in 1924 in Louisville, Kentucky, the Baptist Health family consists of nine hospitals and more than 400 points of care. Baptist Health employed provider network, Baptist Health Medical Group, has nearly 1,500 providers, including more than 750 physicians and more than 740 advanced practice clinicians. Baptist Health's physician network also includes more than 2,000 independent physicians.

Fresenius Kabi USA is a global, integrated pharmaceutical company dedicated to bringing lifesaving medications and solutions to clinicians. For more than 100 years, the company has been a leader in providing high-quality, affordable medications for chronically and critically ill patients.

The Challenge

The use of intravenous (IV) medications is essential to providing patient care in the hospital setting.[1] While administering medications via the IV push route may seem like a straightforward everyday process, it actually carries a high potential for patient harm due to the number of complex manipulations required to administer, compatibility concerns, narrow therapeutic indexes, and challenges with reversing pharmacologic effects of drugs administered by this route.[1] ISMP recommends providing adult IV push medications, to the greatest extent possible, in a ready-to-administer (RTA) form (to minimize the need for manipulation outside of the pharmacy sterile compounding area).[1] An RTA product may reduce the complexity of IV push administration, thus decreasing the likelihood of an error occurring.

Baptist Health recognized the advantages of simplification and decided to standardize to an RTA presentation for several commonly used IV push opioid medications. The Joint Commission revised its pain standards in 2018 to include a leadership standard that reads, "A hospital has a leader or leadership team that is responsible for pain management and safe opioid prescribing and develops and monitors performance improvement activities."[2] By adopting an RTA syringe in secure, tamper-evident packaging, the leadership team believed they could meet their objective of optimizing the clinical workflows surrounding the delivery of IV push morphine, hydromorphone, and fentanyl while reducing the risk of diversion.

> *"Having a ready-to-administer syringe has helped me work more efficiently. I don't have to spend as much time drawing up doses or wasting medication, which allows me to focus on my patients."*
>
> Jay Smith, BSN, RN – Interventional Radiology, Baptist Health Floyd

Dilaudid® (HYDROmorphone HCl) Injection, USP

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full Prescribing Information for complete Boxed Warning.

Fentanyl Citrate Injection, USP

WARNING: RISK OF ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full Prescribing Information for complete Boxed Warning.

Morphine Sulfate Injection, USP

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

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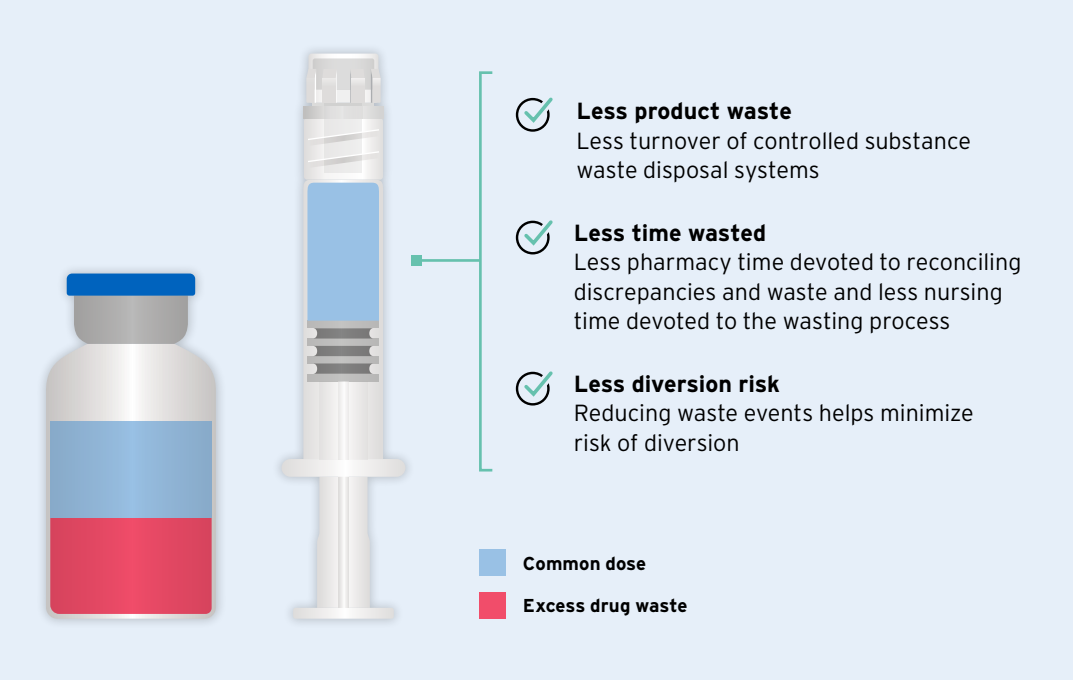
Please see full Important Safety Information, including Boxed Warning, on pages 6–7. Also available at www.simplist-us.com.

The Solution

Reduction in Narcotic Waste

Health-system policies and procedures for handling and disposing of controlled substances vary.[3] Wasting excess medication requires clinicians to dedicate significant time to a process that adds no value to patient care. To better understand what impact reducing narcotic waste could have, Baptist Health partnered with Fresenius Kabi's Medication Technology & Analytics (MTA) team for a complimentary analysis. Fresenius Kabi's MTA team of pharmacists was able to quantify controlled substance waste, labor inefficiency, and automated dispensing system storage space to develop a customized solution to support each hospital with the implementation of the new syringes.



One of the tools used to accomplish this was a narcotic waste calculator developed using *A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste*[3] as a framework. In the study, the authors concluded that significant financial costs are associated with wasting product and skilled labor time. Optimizing product size, taking special note to match product availability with common practice use, would reduce the financial burden placed on health systems.[3]

Conclusions drawn from the study, in addition to the waste calculator results, supported Baptist Health's decision to implement Simplist MicroVault prefilled syringes in sizes that more closely match what is ordered in their hospitals. They understood that this combination had the potential to reduce product waste, resulting in fewer opportunities for diversion.

Automation of Controlled Substance Dispensing

Baptist Health was also seeking novel ways to automate time-consuming operational tasks that inhibit clinicians from spending more time with patients. Required countbacks of controlled substances at the automated dispensing cabinet (ADC) was one task they thought could be targeted for improvement.

Omnicell's Controlled Substance Dispenser (CSD) is an automated unit-dose narcotic dispensing system that ensures nurses' access to the selected dose for their patient, thus eliminating the need for countbacks. The CSD provides a simple and fast controlled substance workflow, which can save hours of nursing time each day.[4] To improve dispensing workflows, they incorporated new cassettes designed specifically for Simplist MicroVault prefilled syringes into their CSD.

The Results

Reduction in Narcotic Waste

To illustrate the impact of implementing these initiatives, Baptist Health leveraged the results from Baptist Health Floyd, a mid-sized hospital within their network of nine locations. By converting IV push administration of commonly used opioid medications to the Simplist MicroVault platform, pharmacy leaders at Baptist Health were able to accomplish their standardization goals while simultaneously making system-wide opioid stewardship performance improvements. Adding products that more closely aligned with clinical practice reduced hydromorphone and fentanyl waste by 79% and 42%, respectively. This change resulted in improved workflows for nursing and pharmacy while significantly reducing time spent wasting.

THE INTERVENTION

Baptist Health Floyd achieved a reduction in overall waste events by adding the following Simplist MicroVault prefilled syringes:

- Dilaudid® (HYDROmorphone Hydrochloride) Injection, USP 0.5 mg per 0.5 mL
- Dilaudid® (HYDROmorphone Hydrochloride) Injection, USP 1 mg per 1 mL
- Fentanyl Citrate Injection, USP 50 mcg per 1 mL

OBSERVED WASTE REDUCTION

79%

Reduction in overall hydromorphone HCl waste events*

Hydromorphone HCl Waste Events Before	
Days Observed	183
Total Waste Events	8,002
Estimated Annualized Waste Events	**15,960**

↓

Hydromorphone HCl Waste Events After	
Days Observed	92
Total Waste Events	846
Estimated Annualized Waste Events	**3,356**

42%

Reduction in overall fentanyl citrate waste events*

Fentanyl Citrate Waste Events Before	
Days Observed	183
Total Waste Events	3,330
Estimated Annualized Waste Events	**6,642**

↓

Fentanyl Citrate Waste Events After	
Days Observed	92
Total Waste Events	974
Estimated Annualized Waste Events	**3,864**

Dilaudid® (HYDROmorphone HCl) Injection, USP

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full Prescribing Information for complete Boxed Warning.

Fentanyl Citrate Injection, USP

WARNING: RISK OF ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full Prescribing Information for complete Boxed Warning.

Morphine Sulfate Injection, USP

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

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Please see full Important Safety Information, including Boxed Warning, on pages 6–7. Also available at www.simplist-us.com.

Automation of Controlled Substance Dispensing

In addition to reducing narcotic waste, Baptist Health also improved the process of dispensing the new syringes by using Simplist MicroVault cassettes for Omnicell's Controlled Substance Dispenser. Simplist MicroVault tamper-evident packaging gave pharmacy leadership peace of mind knowing they were securely dispensing drugs with the highest abuse potential. Combining single-dose dispensing with products that more closely match common practice allowed Baptist Health to decrease opportunities for diversion and reduced waste in three ways:

- Physical amount of drug needing to be wasted
- Required time of two healthcare professionals to waste excess drug
- Time spent counting controlled substances and reconciling waste

Providing an Implementation Roadmap

Streamlining Storage of Simplist®

System-wide change can be a challenge if leadership doesn't have staff buy-in. To ensure a seamless rollout, pharmacy staff collaborated with Fresenius Kabi's Medication Technology & Analytics team to leverage their storage optimization tool, Optilytics. The results provided a roadmap to incorporate the syringes into ADCs simply and efficiently.

Clinical Education

Baptist Health also wanted to be sure every clinician who administers IV push medications was comfortable using the new syringes. Therefore, a new competency was added to the hospital's online training solution, requiring all new hires to review the Simplist Instructions for Use training video prior to using the product.

Fresenius Kabi was able to support the health system by providing an efficient roadmap to implement the products and provide training that ensured clinicians were confident when using Simplist. By partnering with Fresenius Kabi, Baptist Health was able to reduce diversion risk and improve clinician workflow, which ultimately resulted in more time for patient care.

> *"Adopting the Simplist platform in several of our opioid offerings was a win/win proposition. Having ready-to-administer syringes in our most commonly prescribed doses means less time is spent wasting critical medications, which saves nursing time and reduces opportunities for diversion within the organization."*
>
> M. Brandon McLain, PharmD, BCPS, MBA – Director of Pharmacy Operations, Baptist Health

Important Safety Information

Simplist Dilaudid® (HYDROmorphone HCl) Injection, USP

INDICATIONS AND USAGE

DILAUDID INJECTION is indicated for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.

Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve DILAUDID INJECTION for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:

- Have not been tolerated, are not expected to be tolerated
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia

IMPORTANT SAFETY INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- **DILAUDID INJECTION exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions.**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase.**
- **Prolonged use of DILAUDID INJECTION during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.**
- **Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.**

DILAUDID INJECTION is contraindicated in patients with:

- Significant respiratory depression.
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment.
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Known hypersensitivity to hydromorphone, hydromorphone salts, sulfite-containing medications, or any other components of the product.

Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of DILAUDID INJECTION in patients with circulatory shock.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of DILAUDID INJECTION in patients with impaired consciousness or coma.

DILAUDID INJECTION contains sodium metabisulfite. There is a risk of anaphylactic symptoms and life-threatening asthmatic episodes in susceptible people.

Most common adverse reactions are lightheadedness, dizziness, sedation, nausea, vomiting, sweating, flushing, dysphoria, euphoria, dry mouth, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Serotenergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue DILAUDID INJECTION if serotonin syndrome is suspected.

Monoamine Oxidase Inhibitors (MAOIs): Can potentiate the effects of hydromorphone. Avoid concomitant use in patients receiving MAOIs or within 14 days of stopping treatment with an MAOI.

Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with DILAUDID INJECTION because they may reduce analgesic effect of DILAUDID INJECTION or precipitate withdrawal symptoms.

Pregnancy: May cause fetal harm.

Overdosage: Acute overdose with DILAUDID INJECTION can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis, rather than miosis, may be seen with hypoxia in overdose situations.

This Important Safety Information does not include all the information needed to use DILAUDID safely and effectively. Please see full prescribing information, including Boxed Warning, for DILAUDID INJECTION at www.simplist-us.com.

Simplist Fentanyl Citrate Injection, USP

INDICATIONS AND USAGE

Fentanyl Citrate Injection, for intravenous or intramuscular use, is indicated for:

- Analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance and in the immediate postoperative period (recovery room) as the need arises.
- Use as an opioid analgesic supplement in general or regional anesthesia.
- Administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- Use as an anesthetic agent with oxygen in selected high risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

Fentanyl Citrate Injection should be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids. Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF ADDICTION, ABUSE, AND MISUSE; LIFE- THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- **Fentanyl Citrate Injection exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase.**
- **Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of fentanyl.**
- **Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.**

Fentanyl Citrate Injection is contraindicated in patients with a hypersensitivity to fentanyl.

Risks of Skeletal Muscle Rigidity and Skeletal Muscle Movement: Manage with neuromuscular blocking agent. See full prescribing information for more detail on managing these risks.

Severe Cardiovascular Depression: Monitor during dosage initiation and titration.

Serotonin Syndrome: Potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue Fentanyl Citrate Injection if serotonin syndrome is suspected.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, or Head Injury: Monitor for sedation and respiratory depression.

The most common serious adverse reactions were respiratory depression, apnea, rigidity, and bradycardia.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176 option 5 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Concomitant Use of CNS Depressants: May decrease pulmonary arterial pressure and may cause hypotension. See full prescribing information for management instructions. For post-operative pain, start with the lowest effective dosage and monitor for potentiation of CNS depressant effects.

Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with Fentanyl Citrate Injection because they may reduce the analgesic effect of Fentanyl Citrate Injection or precipitate withdrawal symptoms.

Pregnancy: May cause fetal harm.

Lactation: Infants exposed to Fentanyl Citrate Injection through breast milk should be monitored for excess sedation and respiratory depression.

Geriatric Patients: Titrate slowly and monitor for CNS and respiratory depression.

This Important Safety Information does not include all the information needed to use Fentanyl Citrate Injection, safely and effectively. Please see full prescribing information, including Boxed Warning, for Fentanyl Citrate Injection at www.simplist-us.com.

Simplist Morphine Sulfate Injection, USP

INDICATIONS AND USAGE

Morphine Sulfate Injection is an opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Morphine Sulfate Injection for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

IMPORTANT SAFETY INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- **Morphine Sulfate Injection exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions.**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase.**
- **Prolonged use of Morphine Sulfate Injection during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.**
- **Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.**

Morphine Sulfate Injection is contraindicated in patients with:

- Significant respiratory depression.
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment.
- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days.
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Hypersensitivity to morphine.

Cardiovascular Instability: High doses are excitatory. Have Naloxone Injection and resuscitative equipment immediately available.

Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of Morphine Sulfate Injection in patients with circulatory shock.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of Morphine Sulfate Injection in patients with impaired consciousness or coma.

The most serious adverse reactions encountered are respiratory depression, apnea, circulatory depression, respiratory arrest, shock and cardiac arrest. Common frequently observed adverse reactions include: sedation, lightheadedness, dizziness, nausea, vomiting, constipation and diaphoresis.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue Morphine Sulfate Injection if serotonin syndrome is suspected.

Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with Morphine Sulfate Injection because they may reduce analgesic effect of Morphine Sulfate Injection or precipitate withdrawal symptoms.

Pregnancy: May cause fetal harm.

Overdosage: Acute overdose with Morphine Sulfate Injection can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, snoring, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose.

This important safety information does not include all the information needed to use MORPHINE SULFATE INJECTION safely and effectively. Please see full prescribing information, including Boxed Warning, for MORPHINE SULFATE INJECTION at www.simplist-us.com.

Contact us

To learn how narcotic waste is impacting your hospital, contact your Sales Representative or call Customer Service at 1.888.386.1300

www.simplist-us.com

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