MITIGO™ CII
(Morphine Sulfate Injection USP)

Piramal Critical Care is dedicated to providing the most cost-efficient and seamless purchasing options for healthcare providers.

MITIGO™ (Morphine Sulfate Injection USP) is available through the following GPOs:

Vizient GPO Contract Number: RX11030
Premier GPO Contract Number: PPPH18PIR01
HealthTrust Purchasing Group (HPG) GPO Contract Number: HPG-2478
The Resource Group GPO Contract Number: PIRAM-0024775

Available for order through your local wholesaler.

VENDOR	VENDOR ID	MITIGO 10MG/ML 20ML CII NDC: 66794-160-02	MITIGO 25MG/ML 20ML CII NDC: 66794-162-02
AmerisourceBergen		10189461	10189462
Cardinal		5471388	5471396
McKesson		2450930	2450914
Morris & Dickson		410357	410555
Henry Schein		1328860	1328859
HD Smith	7257	5732300	5732318
Besse Medical		52002	52001

HELP MANAGE CHRONIC PAIN TODAY

MitigoMorphine.com

IMPORTANT RISK INFORMATION

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

See full prescribing information for complete boxed warning.

Single-dose neuraxial administration may result in acute or delayed respiratory depression up to 24 hours. Because of the risk of severe adverse reactions when MITIGO is administered by the epidural or intrathecal route of administration, patients must be observed in a fully equipped and staffed environment for at least 24 hours after the initial dose.

Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Patients must be observed in a fully equipped and staffed environment for at least 24 hours after each test dose and, as indicated, for the first several days after surgery.

MITIGO 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.

Prolonged use of MITIGO 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.

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See Important Risk Information on back cover and in accompanying Full Prescribing Information.
For questions, please call: 1.800.414.1901

INDICATIONS AND USAGE

MITIGO (Morphine Sulfate Injection, USP – Preservative-free) is an opioid agonist for use in continuous microinfusion devices and indicated only for intrathecal or epidural infusion in the management of intractable chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Important Risk Information

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CONTRAINDICATIONS

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting in 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 or intolerance to morphine

Neuraxial administration of MITIGO is contraindicated in patients with:

- Infection at the injection microinfusion site
- Concomitant anticoagulant therapy
- Uncontrolled bleeding diathesis

The presence of any other concomitant therapy or medical condition which would render epidural or intrathecal administration of medication especially hazardous

WARNINGS AND PRECAUTIONS

- Risk of Inflammatory Masses: Monitor patients receiving continuous infusion of MITIGO via indwelling intrathecal catheter for new signs or symptoms of neurologic impairment.
- Risk of Tolerance and Myoclonic Activity: Monitor patients for unusual acceleration of neuraxial morphine, which may cause myoclonic-like spasm of lower extremities. Detoxification may be required.
- 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 MITIGO 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 MITIGO in patients with impaired consciousness or coma.

ADVERSE REACTIONS

Most serious adverse reactions were respiratory depression, apnea, circulatory depression, respiratory arrest, shock, and cardiac arrest. Other common frequently observed adverse reactions include: sedation, lightheadedness, dizziness, nausea, vomiting, and constipation.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Hepatic and Renal Impairment: May affect the metabolism and excretion of MITIGO.

For questions regarding Adverse Events, Product Monitoring, and Medical Inquiries for MITIGO™ (morphine sulfate injection, USP-Preservative-free), please call 888.525.8114 or email Global Medical Information at medical.information@piramal.com. You may also report this information to the FDA's MedWatch Reporting System by phone at 1.800.FDA.1088, by facsimile at 1.800.FDA.0178, or by mail using Form 3500 available at www.fda.gov/medwatch.

For additional Important Risk Information, including boxed warning, see enclosed Full Prescribing Information.

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