Duramorph (morphine sulfate) - Drug Summary

Baxter Healthcare Corporation

Jump to Section
- BOXED WARNING
- THERAPEUTIC CLASS
- DEA CLASS
- ADULT DOSAGE & INDICATIONS
- ADMINISTRATION
- ▼ View All Sections...

Related Drug Information ▼

Duramorph
(morphine sulfate)

BOXED WARNING

Risk of severe adverse effects with epidural or intrathecal route; observe patients in a fully equipped and staffed environment for at least 24 hrs after initial dose. Naloxone inj and resuscitative equipment should be immediately available in case of life-threatening or intolerable side effects and whenever therapy is initiated. Intrathecal dosage is usually 1/10 that of epidural dosage. Remove any contaminated clothing and rinse affected area with water if accidental dermal exposure occurs. Associated with risk of overdosage, diversion, and abuse; special measures must be taken to control this product within the hospital/clinic. Do not use if color is darker than pale yellow, if it is discolored in any other way, or if it contains a precipitate.

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Pain

Unresponsive to Non-Narcotic Analgesics:
IV:
Initial: 2-10mg/70kg

Epidural:
Initial: 5mg in the lumbar region
If adequate pain relief is not achieved w/in 1 hr, may give incremental doses of 1-2mg at intervals sufficient to assess effectiveness
Max: 10mg/24 hrs

Intrathecal:
Usual: Single 0.2-1mg dose in the lumbar area; usually 1/10 of the epidural dose
Do not inject more than 2mL of the 5mg/10mL ampul or 1mL of the 10mg/10mL ampul
Repeated inj not recommended; consider alternate routes if pain recurs

ADMINISTRATION

IV/Epidural/Intrathecal route

Proper placement of a needle or catheter in the epidural space should be verified before inj
Limit administration by epidural/intrathecal routes to lumbar area

Intrathecal
May administer a constant IV infusion of 0.6mg/hr naloxone for 24 hrs after intrathecal inj to reduce incidence of potential side effects

HOW SUPPLIED

Inj: 0.5mg/mL, 1mg/mL [10mL]

CONTRAINDICATIONS

Medical conditions that would preclude the administration of opioids by the IV route (acute bronchial asthma, upper airway obstruction).

WARNINGS/PRECAUTIONS

Not for use in continuous microinfusion devices. May be habit forming. Administration should be limited to use by those familiar with respiratory depression management. Rapid IV administration may result in chest-wall rigidity. Prior to any epidural or intrathecal administration, assess for patient conditions (eg, infection at the inj site, bleeding diathesis, anticoagulant therapy) which call for special evaluation of the benefit versus risk potential. Should be administered by or under the direction of a physician experienced in the techniques and familiar with the patient management problems associated with epidural or intrathecal administration. Severe respiratory depression up to 24 hrs following epidural/intrathecal administration reported. Unusual acceleration of neuraxial morphine requirements may occur, which may cause concern regarding systemic absorption and the hazards of large doses; patients may benefit from hospitalization and detoxification. Myoclonic-like spasm of the lower extremities reported with intrathecal doses of >20mg/day; after detoxification, may resume treatment at lower doses. Higher incidence of respiratory depression with intrathecal than epidural use. Seizures may result from high doses; caution with known seizure disorders. Extreme caution with head injury or increased intracranial pressure; pupillary changes (miosis) may obscure the existence, extent, and course of intracranial pathology. High neuraxial doses may produce myoclonic events. Maintain a high index of suspicion for adverse drug reactions when evaluating altered mental status or movement abnormalities. Caution with decreased respiratory reserve (eg, emphysema, severe obesity, kyphoscoliosis, paralysis of the phrenic nerve). Avoid with chronic asthma, upper airway obstruction, or in any other chronic pulmonary disorder. Use caution when administering epidurally to patients with reduced metabolic rates and with hepatic and/or renal dysfunction. Smooth muscle hypertonicity may result in biliary colic. Initiation of neuraxial opiate analgesia is frequently associated with micturition disturbances, especially in males with prostatic enlargement. Monitor patients with reduced circulating blood volume or impaired myocardial function for possible occurrence of orthostatic hypotension. May cause severe hypotension when ability to maintain BP has already been compromised by a depleted blood volume. Avoid abrupt withdrawal. Caution in elderly.

ADVERSE REACTIONS

Respiratory depression/arrest, convulsions, dysphoric reactions, toxic psychoses, pruritus, urinary retention, constipation, lumbar puncture-type headache.

DRUG INTERACTIONS

CNS depressants (eg, alcohol, sedatives, antihistaminics, psychotropic drugs) potentiate depressant effects. Neuroleptics may increase risk of respiratory depression. Monitor for possible occurrence of orthostatic hypotension in patients on sympatholytic drugs. May cause severe hypotension with concurrent administration of drugs such as phenothiazines or general anesthetics.

PREGNANCY AND LACTATION

Category C, safety not known in nursing.

MECHANISM OF ACTION

Opioid analgesic; analgesia involves at least 3 anatomical areas of the CNS: the periaqueductal-periventricular gray matter, the ventromedial medulla, and the spinal cord. Interacts predominantly with μ-receptors distributed in the brain, spinal cord, and trigeminal nerve.

PHARMACOKINETICS

Absorption: (Epidural/Intrathecal) T_{max}=5-10 min (bolus). (Epidural) Rapid; C_{max}=33-40ng/mL; T_{max}=10-15 min. (Intrathecal) C_{max}<1-7.8ng/mL. **Distribution:** Plasma protein binding (36%); found in breast milk. (IV) V_d=1.0-4.7L/kg. **Metabolism:** Hepatic glucuronidation. **Elimination:** Urine (2-12% unchanged), feces (10%). (IV/IM) $T_{1/2}$=1.5-4.5 hrs. (Epidural) $T_{1/2}$=39-249 min.

ASSESSMENT

Assess for patient's general condition and medical status, renal/hepatic impairment, hypersensitivity to drug, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of respiratory depression, seizures, myoclonic events, biliary colic, urinary retention, orthostatic hypotension, drug abuse/dependence, and other adverse reactions.

PATIENT COUNSELING

Inform about risks and benefits of therapy. Inform of adverse reactions that may occur. Instruct to inform physician of other medications being taken. Inform that medication has potential for abuse and dependence.

STORAGE

20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). Protect from light. Do not freeze. Do not heat-sterilize.

Back to top