

עדכוני עלונים

Morphine Injection 1 mg/ml 101-29-28476

אנו מבקשים להביא לידיעתכם שעודכן העלון לרופא

Morphine sulfate: מרכיב פעיל

חוזק: 1mg/ml

התוויה:

For the relief of pain that does not respond to treatment with non-opioid analgesics. Morphine injection is a systemic opioid analgesic administered by the IV, epidural and intrathecal routes. Morphine sulphate administered epidurally or intrathecally provides pain relief for extended periods without attendant loss of motor, sensory or sympathetic function.

העדכונים בעלון לרופא:

(טקסט שהושמט מסומן באדום עם קו חוצה, טקסט שנוסף מסומן בכחול, טקסט המהווה החמרה מודגש בצהוב).

5.8 Opioid induced Hyperalgesia and Allodynia

Opioid Induced Hyperalgesia (OIH) occurs when an opioid analgesic paradoxically causes an increase in pain, or an increase in sensitivity to pain. This condition differs from tolerance, which is the need for increasing doses of opioids to maintain a defined effect [see Dependence (9.3)]. Symptoms of OIH include (but may not be limited to) increased levels of pain upon opioid dosage increase, decreased levels of pain upon opioid dosage decrease, or pain from ordinarily nonpainful stimuli (allodynia). These symptoms may suggest OIH only if there is no evidence of underlying disease progression, opioid tolerance, opioid withdrawal, or addictive behavior. Cases of OIH have been reported, both with short-term and longer-term use of opioid analgesics. Though the mechanism of OIH is not fully understood, multiple biochemical pathways have been implicated. Medical literature suggests a strong biologic plausibility between opioid analgesics and OIH and allodynia. If a patient is suspected to be experiencing OIH, carefully consider appropriately decreasing the dose of the current opioid analgesic or opioid rotation (safely switching the patient to a different opioid moiety) [see Dosage and Administration (2), Warnings and Precautions (5.16)].

6 Adverse Reactions

- Opioid-Induced Hyperalgesia and Allodynia [see Warnings and Precautions (5.8)]

Hyperalgesia and Allodynia:

Cases of hyperalgesia and allodynia have been reported with opioid therapy of any duration [see Warnings and Precautions (5.8)].

Hypoglycemia:

Cases of hypoglycemia have been reported in patients taking opioids. Most reports were in patients with at least one predisposing risk factor (e.g., diabetes).

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9.2 Abuse

Abuse is the intentional non-therapeutic use of a prescription drug, even once, for its desirable psychological or physiological effects.

Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use, (e.g., continuing drug use despite harmful consequences, giving a higher priority given to drug use than to other activities and obligations), and possible tolerance or physical dependence.

Misuse and abuse of Morphine Injections 1 mg/ml increases risk of overdose, which may lead to central nervous system and respiratory depression, hypotension, seizures, and death. The risk is increased with concurrent abuse of Morphine Injections 1 mg/ml with alcohol and/or other CNS depressants. Abuse of and addiction to opioids in some individuals may not be accompanied by concurrent tolerance and symptoms of physical dependence. In addition, abuse of opioids can occur in the absence of addiction.

All patients treated with opioids require careful and frequent reevaluation for signs of misuse, abuse, and addiction, because use of opioid analgesic products carries the risk of addiction even under appropriate medical use. Patients at high risk of Morphine Injections 1 mg/ml abuse include those with a history of prolonged use of any opioid, including products containing morphine, those with a history of drug or alcohol abuse, or those who use Morphine Injections 1 mg/ml in combination with other abused drugs.

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Risks Specific to Abuse of Morphine Injections 1 mg/ml

Abuse of Morphine Injections 1 mg/ml poses a risk of overdose and death. The risk is increased with concurrent use of Morphine Injections 1 mg/ml with alcohol and/or other CNS depressants.

Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

בנוסף נעשו עדכוני עריכה וניסוח קלים.

למידע המלא יש לעיין בעלונים בשלמותם להלן קישור לעלונים הסופיים.

העלונים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות (www.health.gov.il), וניתן גם לקבלם מודפסים ע"י פניה לחברת מעבדות רפא בע"מ בטל': 02-5893939 או בכתובת דוא"ל: RA@rafa.co.il.

בכבוד רב,

מגר' חנה הירש

רוקחת ממונה

מעבדות רפא בע"מ