CONTRAINDICATIONS

DILAUDID® INJECTION (hydromorphone hydrochloride) for intravenous, intramuscular, or subcutaneous use, CII and for which alternate treatments are inadequate. (1)

2.2 Initial Dosage

• Neonatal Opioid Withdrawal Syndrome which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise

Warnings and Precautions (5.2)

all patients regularly for the development of these behaviors and conditions.

Initial Dosage:

• Follow patients for signs and symptoms of respiratory depression and sedation.

Prolonged use of DILAUDID INJECTION during pregnancy can result in neonatal opioid withdrawal syndrome,

for use in patients for whom alternative treatments are inadequate.

the lowest effective dosages and minimum durations of concomitant use. In patients already receiving an opioid analgesic,

while serious, life-threatening, or fatal respiratory depression can occur at any time during the use of DILAUDID INJECTION, the

Monitor such patients closely, particularly when initiating and titrating DILAUDID INJECTION and when DILAUDID INJECTION is

titrate based on clinical response. If an opioid analgesic is initiated in a patient already taking a benzodiazepine or other CNS

While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of DILAUDID INJECTION, the

monitoring of respiratory depression and sedation. (2.2)

with impaired consciousness or coma.

Paralytic ileus

• Monitor patients for signs of urinary retention or reduced gastric motility when

DILAUDID INJECTION is used concomitantly with anticholinergic drugs.

• Known or suspected gastrointestinal obstruction, including paralytic ileus

• Myoclonus, somnolence

• Convulsive disorders

• Addison’s disease

• Hypothyroidism

• Hypoparathyroidism

• Hypoadrenalism

• Anaphylaxis:

Examples:

DILAUDID INJECTION contains alcohol.

•Monitor patients for signs of urinary retention or reduced gastric motility when

Opioids cross the placenta and may produce respiratory depression and both the use of DILAUDID INJECTION and for which

the injection should be given least 2 to 3 minutes. (2.2)

• RISK OF CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

8 USE IN SPECIFIC POPULATIONS

7 DRUG INTERACTIONS

5.9 Risk of Concomitant Use with Benzodiazepines or Other CNS Depressants

5.6 Hepatic Impairment: Initiate treatment with one-fourth to one-half the usual DILAUDID INJECTION starting dose depending on the

8.1 Pregnancy

• DILAUDID INJECTION contains alcohol.

• Monitor patients for signs of urinary retention or reduced gastric motility when

5.1 Addiction, Abuse, and Misuse

• Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks

4 USE IN SPECIFIC POPULATIONS

2 DOSAGE AND ADMINISTRATION

• The usual starting dose of DILAUDID INJECTION is 0.2 mg to 1 mg every 2 to 3 hours. The injection should be given least 2 to 3 minutes. (2.2)

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Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV. The safety and effectiveness of DILAUDID INJECTION in pediatric patients has not been established. Elderly patients (aged 65 years or older) may have increased sensitivity to hydromorphone. In general, use caution.

8.5 Geriatric Use

8.6 Hepatic Impairment

Effects on the Central Nervous System

The pharmacokinetics of hydromorphone are affected by hepatic impairment. Due to increased exposure of hydromorphone, elderly patients with hepatic impairment may require lower doses of DILAUDID INJECTION than those typically given to patients not at risk for hepatic dysfunction. See the Warnings and Precautions section for additional information. (See Dosage and Administration.)

11 DESCRIPTION

Parenteral drug abuse is the intentional non-therapeutic use of a prescription drug, even once, for its rewarding psychological and physical effects. The use of opioids for non-medical purposes is known as “drug seeking behavior.” Opioids are the most commonly abused prescription drugs in the United States, with opioid overdose being the leading cause of death due to drug overdose in the United States. According to the Centers for Disease Control and Prevention, the opioid overdose epidemic continues to crisis levels across the country. Opioid analgesics are commonly prescribed in the management of acute and chronic pain. Prescriptions for opioids increased by about 400% from 1999 to 2013, and the rate of opioid overdose deaths has increased by about 200% from 2010 to 2014.

9.2 Overdose

10 OVERDOSAGE

2. Hold the outer packaging with both hands. To break the tamper evidences seal, hold the tube and the cap close to the seal, and twist until broken. (See Figure 2)

Hyperbilirubinemia and jaundice may occur with severe hepatic impairment. Severe hepatic impairment may develop in patients with obstructive jaundice or associated liver disease. 

DILAUDID INJECTION is available as a sterile, aqueous solution in clear and colorless single-dose prefilled syringes for slow intravenous injection. Each tube contains 0.2 mg, 0.5 mg, 1 mg or 2 mg hydromorphone hydrochloride.

The pharmacokinetics of hydromorphone in patients with severe hepatic impairment has not been studied. A further increase in exposure of hydromorphone would be expected in patients with severe hepatic impairment. Use caution in patients with hepatic impairment, and consider lowering the initial dose and titrating doses more cautiously.

12.2 Incompatibilities

The onset of action of DILAUDID INJECTION may be unexpected due to the effects of the antagonist. Monitoring of the degree of opioid withdrawal and the clinical status of the patient is recommended for 24 hours if the antagonist is administered to a patient previously treated with potent agonist opioids (e.g., morphine, oxycodone, hydrocodone, etc.). If symptoms of opioid withdrawal are observed during the co-administration of an antagonist and an opioid agonist, the antagonist should be discontinued.

DILAUDID INJECTION products carries the risk of addiction even under appropriate medical use.

When DILAUDID INJECTION is used for prolonged periods in children or elderly patients, consideration should be given to the risk-benefit ratio and the close monitoring of the patient, including monitoring for respiratory depression.

Opioids have been shown to have a variety of effects on components of the immune system in vivo and animal models. The mechanism of such changes is not clearly understood. However, it is possible that some of these changes may involve opioid receptors located on immune cells. Some studies have shown that opioids can modulate immune cell function, including the release of cytokines and other mediators.

Hydromorphone has been shown to be a potential clinical tool in the treatment of opioid use disorder. Hydromorphone is a prodrug that is metabolized to its active metabolite, hydromorphone, which is responsible for the analgesic effects of the drug.

The pharmacokinetics of hydromorphone are affected by hepatic impairment. Due to increased exposure of hydromorphone, elderly patients with hepatic impairment may require lower doses of DILAUDID INJECTION than those typically given to patients not at risk for hepatic dysfunction. See the Warnings and Precautions section for additional information. (See Dosage and Administration.)

The pharmacokinetics of hydromorphone in patients with severe hepatic impairment have not been studied. A further increase in exposure of hydromorphone would be expected in patients with severe hepatic impairment. Use caution in patients with hepatic impairment, and consider lowering the initial dose and titrating doses more cautiously.

In patients with hepatic impairment, the pharmacokinetics of hydromorphone may be altered by the development of tolerance to opioid-related adverse reactions. The pharmacokinetics of hydromorphone may also be affected by the development of tolerance to opioid-related adverse reactions. The pharmacokinetics of hydromorphone in patients with severe hepatic impairment has not been studied. A further increase in exposure of hydromorphone would be expected in patients with severe hepatic impairment. Use caution in patients with hepatic impairment, and consider lowering the initial dose and titrating doses more cautiously.