DILAUDID® INJECTION (hydromorphone hydrochloride) for intravenous, intramuscular, or subcutaneous use, CII

FULL PRESCRIBING INFORMATION

Initial U.S. Approval: January 1984

1. USE OF OPIOIDS IN PREGNANCY

1.1 Pregnancy

1.2 Teratogenic Effects

1.2.1 Human Pregnancy

1.2.2 Animal Fertility Studies

1.2.3 Animal Reproduction Studies

1.3 Pregnancy/Breastfeeding

1.4 Labor and Delivery

1.5 Lactation

1.6 Newborn/Infant

2. WARNINGS AND PRECAUTIONS

2.1 Addictions, Abuse, and Misuse

2.2 Life-Threatening Respiratory Depression

2.3 Neonatal Opioid Withdrawal Syndrome

2.4 Neonatal Respiratory Depression

2.5 Management of Labor

2.6 Administration

2.7 Intravenous Administration

2.8 Intramuscular Administration

2.9 Subcutaneous Administration

2.10 Severe Hypotension

2.11 Respiratory Depression

2.12 Seizures

2.13 Chronic Pain: Cautions and Contraindications

2.14 Drug Interactions: Acute and EmergencyOverdose

2.15 Infant

2.16 Procedural Pain

2.17 Postoperative Pain

2.18 Seizure Disorder

2.19 Specific Populations

2.20 Administration During Pregnancy

2.21 Monitoring Patients Requiring Continuous Intravenous Administration

2.22 Administration of Parenteral Opioids in the Presence of Concurrent Moderate or Severe Nonopiod Analgesics

2.23 Administration in Patients Requiring Prolonged Opioid Therapy

2.24 Treatment of Constipation

2.25 Management of Pain

2.26 Pain Management in Invasive Procedures

3. ADVERSE REACTIONS

3.1 Overdose

3.1.1 Resuscitation

3.1.2 Naloxone Administration

3.2 Clinical Trials Experience

3.3上市后经验

3.4 Postmarketing Experience

3.5 Laboratory Tests

4. DRUG INTERACTIONS

4.1 Opioids

4.2 Other Drugs That Alter Serotonergic Transmission

4.3 MAO Inhibitors

4.4 Other Drugs

4.5 In Vitro Studies

4.6 In Vitro Interactions

5. HOW SUPPLIED/STORAGE AND HANDLING

5.1 How Supplied

5.2 Storage

5.3 Handling

6. PATIENT INFORMATION

6.1 Patient Information

7. PATIENT FOCUS

7.1 Patient Instructions

8. LABORATORY TESTS

8.1 Vital Signs

8.2 Electrolytes

8.3 Blood Pressure

8.4 Hematology

8.5 Chemistry

8.6 Opiates

9. References

10. INCIPIENT INFORMATION

10.1 Further Information

10.2 Additional Information

10.3 Additional Sources Of Information

11. PATIENT-CENTERED OUTCOMES SURVEY (P COS)

11.1 Management of Chronic Pain

11.2 Management of Acute Pain

11.3 Opioid Use Disorder

12. CLINICAL PHARMACOLOGY

12.1 Pharmacokinetics

12.2 Mechanism of Action

12.3 Pharmacodynamics

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13.1 Pharmacokinetics

13.2 Mechanism of Action

13.3 Pharmacodynamics
Respiratory depression is the chief risk for elderly patients treated with opioids, and has occurred after large initial doses were administered to patients with severe renal impairment. In general, geriatric patients may be more susceptible to respiratory depression than younger adults due to reduced respiratory reserve. Titrate the dosage of DILAUDID INJECTION slowly in geriatric patients and monitor closely for signs of central nervous system depression.

Patients with moderate hepatic impairment should be started at one-fourth to one-half the recommended starting dose depending on the specific indication to be treated.

The safety and effectiveness of DILAUDID INJECTION in pediatric patients has not been established.

In postmarketing surveillance, an increase in neonatal abstinence syndrome has been reported with hydromorphone use in labor for the management of maternal pain. Neonatal abstinence syndrome has been reported in infants of mothers treated with other opioids during labor. Neonatal abstinence syndrome may be particularly problematic for preterm infants. Use of opioids for labor analgesia may cause respiratory depression in the newborn, and the potential benefits of use should be weighed against the risk of neonatal respiratory depression.

Effects on Fertility

Hydromorphone produces respiratory depression by direct effect on brain stem respiratory centers. Hydromorphone produces respiratory depression by direct effect on brain stem respiratory centers. Hydromorphone is a highly potent, lipid-soluble opioid with high affinity for opioid receptors. Hydromorphone concentration is reduced significantly by acidification of the urine. Hydromorphone overcomes the respiratory depression caused by other opioids. Hydromorphone is a highly potent, lipid-soluble opioid with high affinity for opioid receptors. Hydromorphone concentration is reduced significantly by acidification of the urine. Hydromorphone overcomes the respiratory depression caused by other opioids.

In an animal study, hydromorphone, an opioid agonist, was administered to lactating rats on postnatal days 7 to 21. Hydromorphone concentration was reduced significantly by acidification of the urine. Hydromorphone overcomes the respiratory depression caused by other opioids.