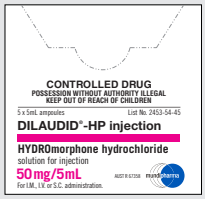
DILAUDID®-HP injection 50 mg

hydromorphone hydrochloride solution for injection

Mundipharma will be **permanently replacing DILAUDID®-HP injection 50mg/5mL** ampoules with a more concentrated solution containing the same strength of drug, hydromorphone hydrochloride **50 mg in 1 mL** ampoules.

OLD FORMULATION



50 mg/5 mL ampoule

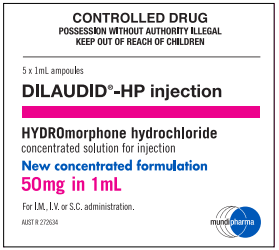
5 mL amber coloured glass

EXPIRY DATE: 31/07/2017

NEW CONCENTRATED FORMULATION

50 mg in 1 mL ampoule

1 mL colourless glass with turquoise, blue, red rings



AVAILABLE FROM 01/08/2017

DILAUDID® injection is indicated for the relief of moderate to severe pain. The High Potency (HP) injection is a concentrated solution intended for use in opioid-tolerant patients.

Please ensure appropriate use according to the approved Product Information, which is available as a leaflet in the pack, or from **https://www.mundipharma.com.au/products/prescription-medicines/**

FOR MORE INFORMATION, CALL MUNDIPHARMA MEDICAL INFORMATION: 1800 188 009

PBS information: DILAUDID injection. Restricted benefit. Severe disabling pain not responding to non-opioid analgesics. Authority required for increased maximum quantities and/or repeats. Refer to PBS Schedule for full Authority Required information.

Please review the Product Information before prescribing. Approved Product Information can be accessed at www.mundipharma.com.au/products/prescription-medicines/

MINIMUM PRODUCT INFORMATION DILAUDID® injection (ampoule: 2 mg/1 mL) DILAUDID®-HP injection (ampoules: 10 mg/1 mL and 50 mg in 1 mL). NAME OF THE MEDICINE: hydromorphone hydrochloride. **INDICATIONS:** DILAUDID® preparations are indicated for the relief of moderate to severe pain. **CONTRAINDICATIONS:** Known hypersensitivity to hydromorphone or to any of the ingredients; respiratory depression with hypoxia or elevated carbon dioxide levels in the blood in the absence of resuscitative equipment, status asthmaticus, paralytic ileus, concurrent MAOIs or within 14 days of such therapy, pregnancy; premature infants and children, or during labour for delivery of premature infants. **PRECAUTIONS:** The major risk of opioid excess is respiratory depression. Use with caution and with a reduced initial dose in the elderly or debilitated and those with renal impairment; hepatic impairment; severe impairment of pulmonary function; myxoedema or hypothyroidism; adrenocortical insufficiency (e.g. Addison's Disease); CNS depression or coma; toxic psychosis; prostatic hypertrophy or urethral stricture; gall bladder disease; acute alcoholism; delirium tremens; pancreatitis or following gastrointestinal surgery. Discontinue immediately if paralytic ileus is suspected or occurs during use. Use with caution in patients with acute abdominal conditions; convulsive disorders; high parenteral hydromorphone doses for cancer and severe pain; head injury, other intracranial lesions, pre-existing increase in intracranial pressure; circulatory shock; ambulatory patients; pre-operatively and within the first 24 hours post-operatively; intra-operatively (injections only); biliary tract procedures; alcoholism and other drug dependencies; hyperalgesia; pregnancy (Category C), lactation. Use with extreme caution in patients with COPD or *cor pulmonale*, patients having a substantially decreased respiratory reserve (e.g. kyphoscoliosis), hypoxia, hypercapnia, or in patients with pre-existing respiratory depression. May affect driving and operating machinery. Physical dependence, tolerance, psychological dependence and abstinence/withdrawal syndrome may occur. Withdraw gradually. Parenteral administration of oral dosage forms may be fatal. **INTERACTIONS WITH OTHER MEDICINES:** CNS depressants (e.g. sedatives or hypnotics, general anaesthetics, phenothiazines, tranquillisers, antiemetics, antidepressants, neuroleptics, other opioids or alcohol), neuromuscular blocking agents. Hydromorphone should not be given to patients taking non-selective MAOIs or within 14 days of stopping such treatment. DILAUDID® injection is physically compatible and chemically stable for at least 24 hours at 25°C protected from light in most common large volume parenteral solutions which do not have a pH > 7 and is incompatible with soluble barbiturates. **ADVERSE EFFECTS:** Adverse effects are similar to those of other opioid agonist analgesics. Very common (≥ 1/10) adverse effects include constipation, dizziness, nausea, somnolence. Common (≥ 1/100 to < 1/10) adverse effects include abdominal pain, anorexia, anxiety, asthenia, confusional state, hyperhidrosis (sweating), dry mouth, dysphoria, euphoria, headache, hypotension, injection site reactions (following parenteral administration only), insomnia, light-headedness, nervousness, pruritus, rash, sedation, urinary retention, vomiting. DOSAGE AND ADMINISTRATION. **WARNING: DILAUDID®-HP INJECTION IS A HIGHLY CONCENTRATED SOLUTION OF HYDROMORPHONE INTENDED FOR USE IN OPIOID-TOLERANT PATIENTS. DO NOT CONFUSE DILAUDID®-HP INJECTION WITH STANDARD PARENTERAL FORMULATIONS OF DILAUDID® OR OTHER OPIOIDS. OVERDOSE AND DEATH COULD RESULT.** Adults: *Recommended initial dose for non opioid-tolerant patients:* IM or SC: 1 to 2 mg every 4 to 6 hours; IV: 0.5 to 1.0 mg (given slowly over 2 to 3 minutes); Patient-controlled analgesia (PCA): Limited data available. One literature regimen is as follows: Adequate analgesia should be established prior to commencement of the PCA. A background continuous IV infusion of 0.1 mg/hour should be used together with patient-administered bolus doses of 0.2 mg at no more than 5 minutely intervals and up to a maximum of 1.2 mg/hour; Continuous IV infusion: Limited data available. An infusion of up to 0.3 mg/hour has been used in a small number of patients. *Patients currently receiving opioids:* The dose should be selected and adjusted so that at least 3-4 hours of pain relief is achieved. The starting dose should be based on the prior daily opioid dose. Once the total daily dosage of hydromorphone has been estimated, it should be divided into the desired number of doses. *Chronic pain:* doses should be administered around-the-clock. A supplemental dose of 5-15% of the total daily usage may be administered every two hours on an 'as-needed' basis. Elderly: May require lower doses of DILAUDID® preparations. Children: Safety and efficacy have not been established in children. **DATE OF FIRST INCLUSION IN THE ARTG:** 20 August 1999. **DATE OF MOST RECENT AMENDMENT:** 16 Sep 2015 | **Mundipharma Pty Limited** ABN 87 081 322 509. 88 Phillip Street, Sydney NSW 2000. Tel. 1800 188 009. ® DILAUDID is a registered trade mark. FD17030 ORBIS AU-3865 Mar17

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