

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

DILAUDID[®]

HYDROMORPHONE Hydrochloride Tablets and Sterile Solution for Injection

Read this carefully before you start taking **DILAUDID** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DILAUDID**.

Serious Warnings and Precautions

- Even if you take DILAUDID as prescribed you are at a risk for opioid addiction, abuse, and misuse. This can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse you should speak to your prescriber (e.g., health care professional).
- When you take DILAUDID tablets they must be swallowed whole. Do not cut, break, crush, chew, or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.
- Life-threatening breathing problems can happen while taking DILAUDID, especially if not take as directed. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.
- You should never give anyone your DILAUDID. They could die from taking it. If a person has not been prescribed DILAUDID, taking even one dose can cause a fatal overdose. This is especially true for children, and for an adult who is not already taking opioids continuously.
- If you took DILAUDID while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:
 - has changes in their breathing (such as weak, difficult or fast breathing)
 - is unusually difficult to comfort
 - has tremors (shakiness)
 - has increased stools, sneezing, yawning, vomiting, or feverSeek immediate medical help for your baby.
- Taking DILAUDID with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

What is DILAUDID used for?

DILAUDID is a pain medication used to control pain.

How does DILAUDID work?

DILAUDID contains HYDROMORPHONE which is a pain medication belonging to the class of drugs known as opioids which includes codeine, fentanyl, morphine, and oxycodone. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

DILAUDID Injection is used to treat severe pain in patients who need an opioid administered by injection. This is given under the skin, into the muscle or vein in doses or concentrations that are higher than those usually needed.

What are the ingredients in DILAUDID?

Medicinal ingredient: HYDROMorphone hydrochloride

Non-medicinal ingredients in tablet: lactose anhydrous, magnesium stearate.

In addition, the tablet strengths listed below contain the following dyes:

1 mg: D&C Yellow No.10 Lake, FD&C Blue No. 1 Lake

2 mg: D&C Red No. 30 Lake, D&C Yellow No. 10 Lake

4 mg: D&C Yellow No. 10 Lake

Non-medicinal ingredients in sterile solution for injection: sodium citrate, citric acid

DILAUDID comes in the following dosage forms:

Immediate Release Tablets: 1 mg, 2 mg, 4 mg and 8 mg.

Sterile solution for injection: 2 mg/mL.

Do not use DILAUDID if:

- your health care professional did not prescribe it for you.
- you are allergic to HYDROMorphone, or any of the other ingredients in DILAUDID tablets or injection (see What are the ingredients in DILAUDID?).
- you can control your pain by the occasional use of other pain medications. This includes those available without a prescription.
- you have severe asthma, trouble breathing, or other lung problems.
- you have any heart problems.
- you have bowel blockage or narrowing of the stomach or intestines.
- you have a condition where the bowel does not work properly (ileus) or have severe pain in your abdomen.
- you have increased pressure in your skull or have a head injury.
- you have epilepsy (seizures) or a history with epilepsy.
- you have a brain tumor.
- you suffer from alcoholism or alcohol withdrawal.
- you are taking or have taken within the past 2 weeks a Monoamine Oxidase Inhibitor (MOI) (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline).
- you are going to have a surgery or operation or have had a surgery in the last 24 hours.
- you are pregnant or planning to become pregnant or you are in labour.
- you are breastfeeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DILAUDID. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse.
- have severe kidney, liver, or lung disease.
- have been told you are at risk of having heart problems or seizures.
- have heart disease.
- have low blood pressure.
- have a history of sleep apnea.
- have had problems with your mood (such as depression or anxiety), hallucinations, or other mental health problems.
- suffer from chronic or severe constipation.

- have problems with your adrenal or prostate gland.
- suffer from migraines.
- are pregnant or planning to become pregnant or are in labour.
- are breastfeeding or planning to breastfeed.
- have a sleep disorder which causes pauses in breathing or shallow breathing while sleeping (sleep apnea).
- are planning on drinking alcohol. Drinking alcohol while taking DILAUDID may cause dangerous side effects, including death. Do NOT drink alcohol while taking DILAUDID.
- have a condition that causes weakness or frailty.

Other warnings you should know about:

Opioid dependence and addiction: Like any opioid, DILAUDID may cause mental and physical dependence. Hydromorphone hydrochloride also has the potential to cause addiction. There are important differences between physical dependence and addiction. Tolerance means that, over time, a higher dose may be needed to get the same level of pain relief. It is important that you talk to your healthcare professional if you have questions or concerns about addiction, physical dependence, or tolerance. Your healthcare professional should prescribe and administer DILAUDID with the same degree of caution appropriate to the use of other oral opioid medications. It is not recommended to use these products for a long period of time.

Pregnancy, nursing, labour, and delivery: Do not use DILAUDID while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. DILAUDID can then cause life-threatening breathing problems in your unborn baby or nursing infant. Your healthcare professional will determine if the benefits of using DILAUDID outweigh the risks to your unborn baby or breastfeeding infant.

If you are pregnant and are taking DILAUDID, it is important that you don't stop taking your medication all of a sudden. If you do, it can cause a miscarriage or a still-birth. Your health care professional will monitor and guide you on how to slowly stop taking DILAUDID. This may help avoid serious harm to your unborn baby.

Driving and using machines: Before you do tasks, which may require special attention, you should wait until you know how you react to DILAUDID. DILAUDID can cause:

- drowsiness
- dizziness or
- light-headedness

This can usually occur after you take your first dose and when your dose is increased.

Disorder of the adrenal gland: You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak, or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your health care professional may do tests, give you another medication, and slowly take you off DILAUDID.

Serotonin toxicity (also known as serotonin syndrome): DILAUDID can cause serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles, and digestive system work. You may develop serotonin toxicity if you take DILAUDID with certain anti-depressants, migraine medications or muscle relaxants medications.

Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Sexual Function/Reproduction: Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

Sleep Apnea: Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your health care professional if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

Worsened pain: Taking opioids for pain can sometimes have the unintended effect of making your pain feel worse (opioid-induced hyperalgesia) even though your opioid dose has been unchanged or increased. This can also include feeling pain in new places in your body, or feeling pain from something that would not normally hurt, for example, feeling pain from clothing touching your skin. Tell your healthcare professional if you notice a change like this in your pain while you are taking DILAUDID.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

Serious Drug Interactions

Taking DILAUDID with the following medicines can cause serious side effects, including breathing problems that can lead to death:

- alcohol, including prescription and non-prescription medications that contain alcohol. Do NOT drink alcohol while you are taking DILAUDID. It can lead to:
 - drowsiness,
 - unusually slow or weak breathing,
 - serious side effects or,
 - a fatal overdose.
- Monoamine Oxidase Inhibitors (MAOI), used to treat depression. Do NOT take DILAUDID with MAOI's or if you have taken an MAOI in the last 14 days.
- benzodiazepines, medicines used to help you sleep or that help reduce anxiety (e.g., diazepam, lorazepam, alprazolam).
- antiepileptics, used to treat and prevent seizures (e.g., gabapentin, carbamazepine, phenytoin, oxcarbazepine, phenobarbital).
- drugs used to treat nerve pain (e.g., pregabalin)
- drugs used to prevent and control seizures in the treatment of epilepsy (e.g., gabapentin)
- other sedative drugs which may enhance the drowsiness caused by DILAUDID.

The following may interact with DILAUDID:

- alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not**

drink alcohol while you are taking DILAUDID. It can lead to:

- drowsiness
- unusually slow or weak breathing
- serious side effects or
- a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by DILAUDID
- general anesthetics (medicines used during surgery)
- drugs used to treat serious mental or emotional disorders, such as schizophrenia
- antihistamines, medicines used to treat allergies
- anti-emetics (for the prevention of vomiting)
- muscle relaxants drugs used to treat muscle spasms and back pain (e.g., baclofen).
- anticoagulants (blood thinners)
- some heart medications (such as beta blockers)
- drugs used to treat migraines (e.g. triptans)
- St. John's Wort

How to take DILAUDID:

Take DILAUDID tablets and injection:

- usually every 4 to 6 hours, or as directed by your health care professional
- with a full glass of water

DILAUDID tablets:

Swallow whole. Do not cut, break, crush, chew or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.

DILAUDID injection:

Should be visually inspected prior to use. Only clear solutions free from particles should be used. The injection should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded.

Usual Dose:

Your dose is tailored/personalized just for you. Be sure to follow your health care professional's dosing instructions exactly. Do not increase or decrease your dose without consulting your health care professional.

Your health care professional will prescribe the lowest dose that works to control your pain. It is recommended that you only take DILAUDID for up to 7 days. If you need to take DILAUDID for longer, your health care professional will determine the best dose for you to lower the risk of side effects and overdose. Higher doses can lead to more side effects and a greater chance of overdose.

Review your pain regularly with your health care professional to determine if you still need DILAUDID. Be sure to use DILAUDID only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking DILAUDID, tell your health care professional immediately.

Stopping your Medication:

If you have been taking DILAUDID for more than a few days, you should not stop taking it all of a sudden. Your health care professional will monitor and guide you on how to slowly stop taking DILAUDID. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches

- diarrhea
- goosebumps
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)
- having trouble sleeping
- an unusual increase in sweating
- heart palpitations
- an unexplained fever
- weakness
- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking DILAUDID.

Refilling your Prescription for DILAUDID:

A new written prescription is required from your health care professional each time you need more DILAUDID. Therefore, it is important that you contact your health care professional before your current supply runs out.

Only obtain prescriptions for this medication from the health care professional in charge of your treatment. Do not seek prescriptions from other health care professionals unless you switch to another health care professional for your pain management.

Overdose:

If you think you have taken too much DILAUDID, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

Missed Dose:

If you miss one tablet dose, take it as soon as possible. However, if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once. If you miss several doses in a row, talk to your health care professional before restarting your medication.

What are possible side effects from using DILAUDID?

These are not all the possible side effects you may feel when taking DILAUDID. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- drowsiness
- insomnia
- dizziness
- fainting
- nausea, vomiting, or a poor appetite
- dry mouth
- headache
- problems with vision
- weakness, uncoordinated muscle movement
- lack of muscle strength
- itching
- light-headedness
- sweating
- constipation
- confusion
- anxiety
- abdominal pain
- injection site reaction
- low sex drive, impotence (erectile dysfunction), infertility

Talk with your health care professional or pharmacist about ways to prevent constipation when you start using DILAUDID.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			✓
Respiratory Depression: slow, shallow or weak breathing.			✓
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea.			✓

Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
Fast, Slow or Irregular Heartbeat: heart palpitations.		✓	
Low Blood Pressure: dizziness, fainting, light-headedness.	✓		
Serotonin toxicity (also known as serotonin syndrome): agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

- **Keep unused or expired DILAUDID in a secure place to prevent theft, misuse, or accidental exposure.**
- Store tablets and sterile solution for injection at room temperature (15° - 25°C). Keep in a dry place. Protect sterile solution for injection from light.
- **Keep DILAUDID under lock, out of sight and reach of children and pets.**
- **Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes DILAUDID, get emergency help right away.**

Disposal:

DILAUDID should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about DILAUDID:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://health->

products.canada.ca/dpd-bdpp/); the manufacturer's website <http://www.purdue.ca>, or by calling 1-800-387-4501.

This leaflet was prepared by Purdue Pharma.

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