

DILAUDID® and DILAUDID®-HP

2 mg in 1mL, 10 mg in 1mL and 50 mg in 1mL Injections

Hydromorphone hydrochloride (*hi-dro-morf-own hi-dro-klor-ide*)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DILAUDID and DILAUDID-HP injections.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the benefits of you using this medicine against the risks it may have for you.

If you have any concerns about this medicine, talk to your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What DILAUDID and DILAUDID-HP injections are used for

DILAUDID and DILAUDID-HP injections contain hydromorphone hydrochloride.

Hydromorphone belongs to a group of medicines called opioid analgesics.

DILAUDID and DILAUDID-HP injections are used to relieve moderate to severe pain. They can be given as a single injection, or as an infusion into a vein, or as an injection into the tissue under the skin, or as an injection into the muscle.

Opioid analgesics have been used to treat pain for many years. Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

As with all strong painkillers, your body may become used to you having hydromorphone. Being given it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop having hydromorphone suddenly, so it is important that you are given DILAUDID and DILAUDID-HP injections exactly as directed by your doctor.

This medicine is only available with a doctor's prescription.

Before you have DILAUDID or DILAUDID-HP injections

When you must not have it

You should not have DILAUDID or DILAUDID-HP injections if you:

- suffer from shallow or difficult breathing or have any acute breathing problems such as acute asthma
- have severe abdominal pain with bloating, cramps or vomiting
- have a condition where your small bowel does not work properly
- take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks
- have been prescribed DILAUDID-HP injection and you have not used any opioid medicine before.

You should not have DILAUDID or DILAUDID-HP injections if you are allergic to hydromorphone, opioid analgesics, or any of the ingredients listed at the end of this leaflet.

Do not use this medicine after the expiry date (EXP) printed on the pack.

If you have it after the expiry date has passed, it may not work very well or may no longer be sterile.

Do not use this medicine if the packaging is damaged or shows signs of tampering or if the solution in the ampoule shows any visible signs of deterioration.

Do not have this medicine during labour for the delivery of premature infants.

Hydromorphone given to the mother can cause breathing problems in the newborn, especially premature babies.

Do not have this medicine if you are pregnant or intend to become pregnant whilst having this medicine.

Like most medicines of this kind, DILAUDID and DILAUDID-HP injections should not be given during pregnancy. Your doctor will discuss the risks of having it if you are pregnant.

Do not give this medicine to a child, and especially not to a premature newborn.

Safety and efficacy in children have not been established.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- are severely drowsy or have a reduced level of consciousness
- heart problems or heart disease
- chronic lung disease
- have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- convulsions, fits or seizures
- head injury, brain tumour or increased pressure in your head
- are about to have surgery or have had surgery in the last 24 hours
- recent gastrointestinal surgery
- chronic liver or kidney disease
- low blood pressure including from having low blood volume
- feeling faint or dizzy upon standing
- increased prostate size or difficulty passing urine
- problems with or recent surgery of your bile duct
- problems with your gall bladder
- inflammation of the pancreas
- adrenal glands not working properly
- underactive thyroid gland
- severe mental condition involving losing contact with reality or an inability to think clearly
- an addiction or history of abuse of alcohol, opioids or other drugs.

Tell your doctor if you are breastfeeding or planning to breastfeed.

DILAUDID and DILAUDID-HP injections should not be given to breastfeeding women

as hydromorphone may pass into the breast milk and can affect the baby.

If you have not told your doctor about any of the above, tell them before you have DILAUDID or DILAUDID-HP injections.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and DILAUDID or DILAUDID-HP injections may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders. Medicines for depression belonging to a group called monoamine oxidase inhibitors must be stopped 14 days before an injection or infusion of DILAUDID or DILAUDID-HP is given
- medicines to help you sleep
- medicines to put you to sleep during an operation or procedure
- medicines to relax your muscles
- medicines to stop nausea and vomiting e.g. metoclopramide or prochlorperazine
- other pain relievers including other opioids
- alcohol

These medicines and alcohol may be affected by DILAUDID or DILAUDID-HP injections, may affect how well DILAUDID and DILAUDID-HP injections work or may increase side effects. You may need to use different amounts of your medicines or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while having this medicine.

How DILAUDID and DILAUDID-HP injections are given

How much is given

Your doctor will decide the appropriate dose for you.

How it is given

A doctor or nurse will usually prepare and administer the injection or infusion.

DILAUDID and DILAUDID-HP injections can be given as a single injection or infusion into the vein. It can also be administered through a fine needle into the tissue under the skin or into the muscle.

Your doctor will decide the most appropriate way for you to have hydromorphone. Using this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

When it is given

You should be given DILAUDID or DILAUDID-HP injections as directed by your doctor.

If you begin to experience pain, tell your doctor as your dosage may have to be reviewed.

How long it is given for

You should be given this medicine for as long as directed by your doctor.

If you stop having this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea (feeling sick), stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping, nervousness or restlessness
- increased sweating and yawning
- weakness

If you forget to have it

If you forget to have a dose, contact your doctor or pharmacist for advice.

Do not have a double dose to make up for the dose you have missed.

Having extra medicine will increase the chance of an unwanted side effects.

If you have received too much (overdose)

Immediately contact your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have had too much DILAUDID or DILAUDID-HP injection. Keep telephone numbers for these places handy.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If someone has had an overdose they may experience difficulties in breathing, become drowsy and tired, have constricted pupils, lack muscle tone, have cold or clammy skin, have very low blood pressure or slow heart rate and possibly may even become unconscious or die.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

While you are having DILAUDID or DILAUDID-HP injections

Things you must do

You should be given DILAUDID or DILAUDID-HP injections exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and pharmacist you are having DILAUDID or DILAUDID-HP injections.

Tell any other doctors, dentists and pharmacists who treat you that you are having this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are having this medicine.

It may affect other medicines used during surgery.

If you become pregnant while having this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if your pain is getting worse. Also discuss any problems or difficulties you have while you are having this medicine with your doctor.

Tolerance to hydromorphone may develop which means that the effect of the medicine may decrease. If this happens, your doctor may review the dose so that you get adequate pain relief.

Things you must not do

Do not use DILAUDID or DILAUDID-HP injections to treat any other complaint unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop using this medicine, exceed the dose recommended or change the dose without checking with your doctor.

Over time your body may become used to hydromorphone so if you stop having it suddenly, your pain may worsen and you may have unwanted side effects such as withdrawal symptoms. This is called physical dependence.

If you need to stop having this medicine, your doctor will gradually reduce the amount you have each day, if possible, before stopping the medicine completely.

Do not drink alcohol while you are having this medicine.

Drinking alcohol while using this medicine may make you feel more sleepy and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Things to be careful of

Tell your doctor if you find that you cannot concentrate or that you feel more sleepy than normal when you start having this medicine or when the dose is increased.

This feeling should wear off after a few days.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Do not drive or operate machinery until you know how DILAUDID or DILAUDID-HP injections affect you.

As with other opioid analgesics, DILAUDID and DILAUDID-HP injections may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. Discuss these aspects and any impact on your driving or operating machinery with your doctor.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as unsteadiness, dizziness, drowsiness or confusion which may increase the risk of a fall.

Tell your doctor if you suffer from nausea or vomiting when having DILAUDID or DILAUDID-HP injections.

Your doctor may be able to give you some medicine to help.

Tell your doctor if having DILAUDID or DILAUDID-HP injections causes constipation.

Your doctor can advise you about your diet, the proper use of laxatives and other ways to help manage constipation.

There is potential for abuse of hydromorphone and the development of addiction to hydromorphone. It is important that you discuss this issue with your doctor.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious but most of the time they are not. Your doctor has weighed the risks of this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

Not everybody experiences them.

Tell your doctor as soon as possible if you do not feel well while you are having DILAUDID or DILAUDID-HP injections.

This medicine helps most people with moderate to severe pain, but it may have unwanted side effects in some people. Other side effects not listed here may also occur.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- mild abdominal problems such as, feeling nauseous (feeling sick), loss of appetite, constipation or diarrhoea
- dry mouth or changes in taste
- feeling agitated, nervous or anxious
- have trouble sleeping
- trouble with your balance
- problems with your eyesight
- skin rash, itching or sweating
- uncoordinated muscle movements and stiffness, tremor, tingling and numbness
- feeling faint
- swelling, including but not only, of the legs or ankles
- redness and soreness at site of injection
- chills
- erectile dysfunction.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- stomach discomfort or cramps, vomiting, indigestion or abdominal pain
- changes in mood
- light-headedness, fainting or dizziness especially when standing up
- drowsiness or feeling extremely sedated
- feeling disorientated and having nightmares
- slow or noticeable heartbeats
- headache, confusion or hallucinations
- unusual weakness or loss of strength
- difficulty passing urine, pain or feeling the need to urinate urgently.

The above list includes serious side effects that may require medical treatment.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- your breathing slows or weakens
- you have an allergic reaction: shortness of breath, wheezing, shallow or difficult breathing; swelling of the tongue, throat,

- face, lips or other parts of the body; rash, itching or hives on the skin
- seizures, fits or convulsions
 - fast or irregular heartbeats

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

When seeking medical attention, take this leaflet and any remaining medicine with you to show the doctor.

After having it

Storage

DILAUDID® or DILAUDID®-HP injections should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded.

If you are having DILAUDID® or DILAUDID®-HP injections in hospital, the ampoules will be stored in the pharmacy or on the ward.

If you have some of this medicine at home, keep the ampoules in a cool, dry place where the temperature stays below 30°C and protected from light.

Do not store it or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car.

Heat can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop having this medicine, or the expiry date has passed, ask your pharmacist how to dispose of medicines no longer required.

Product description

What it looks like

DILAUDID® 2 mg injection contains 1 mL of a clear, colourless to pale yellow solution in a clear glass ampoule marked with turquoise-yellow-turquoise rings. Each carton contains 5 ampoules.

DILAUDID®-HP 10 mg injection contains 1 mL of a clear, colourless to pale yellow solution in a clear glass ampoule marked with turquoise-turquoise-red rings. Each carton contains 5 ampoules.

DILAUDID®-HP 50 mg concentrated injection contains 1 mL of a clear, colourless to pale yellow solution in a clear glass ampoule marked with turquoise-blue-red rings. Each carton contains 5 ampoules.

Ingredients

The active ingredient in DILAUDID® and DILAUDID®-HP is hydromorphone hydrochloride.

DILAUDID® 2 mg injection contains 2 mg hydromorphone hydrochloride in 1 mL of solution.

DILAUDID®-HP 10 mg injection contains 10 mg hydromorphone hydrochloride in 1 mL of solution.

DILAUDID®-HP 50 mg concentrated injection contains 50 mg hydromorphone hydrochloride in 1 mL of solution.

The inactive ingredients are:

- sodium citrate dihydrate

- citric acid
- sodium chloride
- hydrochloric acid or sodium hydroxide to adjust pH
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or other azo dyes.

Sponsor

DILAUDID® and DILAUDID®-HP injections are supplied in Australia by:

Mundipharma Pty Limited
ABN 87 081 322 509
88 Phillip Street
Sydney NSW 2000
Phone: 1800 188 009

® DILAUDID is a registered trade mark

This leaflet was updated in October 2017.

The Australian registration numbers are:

DILAUDID® 2 mg in 1mL injection AUST R 272632

DILAUDID®-HP 10 mg in 1mL injection AUST R 272633

DILAUDID®-HP 50 mg in 1mL concentrated injection AUST R 272634

Orbis RA-3381