

DILAUDID®

Tablets and oral liquid

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 tablets or oral liquid.

It does not contain all of 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 DILAUDID tablets or oral liquid 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 with the medicine.

You may need to read it again.

What DILAUDID tablets & oral liquid are taken for

DILAUDID tablets and oral liquid contain hydromorphone hydrochloride. Hydromorphone belongs to a group of medicines called opioid analgesics.

DILAUDID tablets or oral liquid are taken to relieve moderate to severe pain.

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 taking hydromorphone. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking hydromorphone suddenly, so it is important to take it exactly as directed by your doctor.

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

Before you take it

When you must not take it

Do not take DILAUDID tablets or oral liquid if you:

- suffer from shallow or difficult breathing or have any 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.

Do not take DILAUDID tablets or oral liquid if you are allergic to hydromorphone, opioid painkillers, or any of the ingredients listed at the end of this leaflet.

The tablets contain lactose so consider this if you are lactose intolerant.

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

If you take it after the expiry date has passed, it may not work very well.

Do not take it if the packaging is damaged or shows signs of tampering.

Do not take 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 take this medicine if you are pregnant or intend to become pregnant whilst taking this medicine.

Like most medicines of this kind, DILAUDID tablets or oral liquid are not recommended to be taken during pregnancy. Your doctor will discuss the risks of taking 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 your gall bladder
- problems with or recent surgery of your bile duct
- 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 tablets or oral liquid should not be taken by breastfeeding women as hydromorphone may pass into the breastmilk and can affect the baby.

If you have not told your doctor about any of the above, tell them before you take DILAUDID tablets or oral liquid.

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 tablets or oral liquid 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 DILAUDID tablets or oral liquid are taken
- 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 tablets or oral liquid, may affect how well DILAUDID tablets or oral liquid 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 taking this medicine.

How to take DILAUDID tablets or oral liquid

How much to take

Your doctor will tell you exactly how much to take.

Follow the instructions given to you by your doctor or pharmacist exactly.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How to take it

Swallow DILAUDID tablets with a glass of water.

Accurately measure the dose of DILAUDID oral liquid required.

Using a medicine measure such as a measuring glass or oral syringe, will make sure that you get the correct dose. You can buy a medicine measure from a pharmacy.

Your doctor will choose the best DILAUDID preparation to give you. If you have trouble swallowing your tablets, talk to your doctor.

You must only take DILAUDID tablets or oral liquid by mouth.

Taking these medicines in a manner other than that prescribed by your doctor can be harmful to your health.

When to take it

Take DILAUDID tablets or oral liquid every 4 hours or as directed by your doctor.

Take these medicines at about the same times each day.

Take DILAUDID tablets or oral liquid either with or without food but take it the same way every time. If you begin to experience pain, tell your doctor as your dosage may have to be reviewed.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you stop taking 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, tremor, shivering or fever
- trouble sleeping, nervousness or restlessness
- increased sweating and yawning

- weakness.

If you forget to take it

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

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

Taking extra medicine will increase the chance of unwanted side effects.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take 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 taken too many DILAUDID tablets or taken too much DILAUDID oral liquid. 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 takes 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 taking it

Things you must do

Take DILAUDID tablets or oral liquid exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and

pharmacist you are taking DILAUDID tablets or oral liquid.

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

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

It may affect other medicines used during surgery.

If you become pregnant while taking 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. Always discuss any problems or difficulties you have while you are taking 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.

Keep enough DILAUDID tablets or oral liquid with you to last over weekends and holidays.

Things you must not do

Do not take DILAUDID tablets or oral liquid 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 taking 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 taking 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 taking this medicine, your doctor will gradually reduce the amount you take each day,

if possible, before stopping the medicine completely.

Do not drink alcohol while you are taking this medicine.

Drinking alcohol while taking 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 taking 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 tablets or oral liquid affects you.

As with other opioid analgesics, DILAUDID tablets or oral liquid 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 taking DILAUDID tablets or oral liquid.

If you vomit after your dose, your pain may come back as you may not have absorbed your medicine. Your doctor may be able to give you some medicine to help.

Tell your doctor if taking DILAUDID tablets or oral liquid 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 taking DILAUDID tablets or oral liquid.

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
- 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 difficulty 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 taking it

Storage

Keep your medicine in its original container in a cool, dry place where the temperature stays below 25°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 and damp 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 taking 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® tablets are available in three strengths:

- 2 mg tablets are round, light-orange tablets (marked with 2 on one side and a "D" logo on the reverse)
- 4 mg tablets are round, light-yellow tablets (marked with 4 on one side and a "D" logo on the reverse)

- 8 mg tablets are white, triangle-shaped tablets (one side marked with two small "D" logos, one on each side of a break line and 8 on reverse).

DILAUDID® tablets are available in opaque plastic bottles containing 20 tablets.

DILAUDID® oral liquid is a clear, colourless to pale yellow, slightly viscous solution and is available in one strength (1 mg/mL).

Each amber glass bottle contains 473 mL.

Each amber PET bottle contains 200 mL.

Ingredients:

DILAUDID® tablets

Active ingredient:

- 2 mg tablet contains 2 mg hydromorphone hydrochloride
- 4 mg tablet contains 4 mg hydromorphone hydrochloride
- 8 mg tablet contains 8 mg hydromorphone hydrochloride

Inactive ingredients:

- lactose anhydrous
- magnesium stearate.

In addition, the 2 mg and 4 mg tablets contain quinoline yellow aluminium lake (CI 47005) and the 2 mg tablet also contains vat red 1 aluminium lake (CI 73360).

DILAUDID® oral liquid

One mL contains 1 mg hydromorphone hydrochloride as the active ingredient.

Inactive ingredients are sucrose, glycerol, propyl hydroxybenzoate (preservative), methyl hydroxybenzoate (preservative) and water.

Supplier

DILAUDID® tablets and DILAUDID® oral liquid 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 trade mark of MUNDIPHARMA.

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The Australian registration numbers are:

DILAUDID® tablets

2mg: AUST R 67353

4mg: AUST R 67354

8mg: AUST R 67355

DILAUDID® oral liquid

1mg/mL: AUST R 67360

Orbis RA-0252