

ORDINE® oral solution

Morphine hydrochloride trihydrate (mor-fean hi-dro-klor-ide try-hi-drate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ORDINE oral solution.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ORDINE oral solution is taken for

ORDINE oral solution contains morphine hydrochloride trihydrate. Morphine belongs to a group of medicines called opioid analgesics.

ORDINE oral solution is used to relieve severe pain when other forms of treatment have not been effective. It may also be used to improve sleep where sleeplessness is due to pain.

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

As with all strong painkillers, your body may become used to you taking ORDINE oral solution. Taking it may result in physical dependence. Physical dependence

means that you may experience withdrawal symptoms if you stop taking morphine 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 ORDINE oral solution if you:

- have any breathing problems such as acute asthma, respiratory depression (breathing slows or weakens) or other obstructive airways disease
- are severely drowsy or have a reduced level of consciousness
- suffer from irregular heart beats or changes in the way the heart beats
- have heart problems or heart disease including if due to long-term lung disease
- have just consumed a large amount of alcohol, regularly consume large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- suffer from convulsions, fits or seizures, tetanus caused by excitement of your spinal cord or strychnine poisoning
- have a head injury, brain tumour, increased pressure in your head or spine
- have severe abdominal pain

- have a condition where your stomach empties more slowly than it should or your small bowel does not work properly
- have an obstruction of the bowel or a condition where it could occur
- have had recent surgery of your gall bladder or bile duct or to join two hollow organs together
- are about to have surgery on your spine for pain relief in the next 24 hours
- have severe kidney or liver disease or a disease of the brain caused by liver disease
- take medicine for depression called a 'monoamine oxidase inhibitor' or you have taken any in the last two weeks.

Do not take ORDINE oral solution if you are allergic to morphine, opioid analgesics, or any of the ingredients listed at the end of this leaflet.

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 torn or shows signs of tampering.

Do not take ORDINE oral solution if you are pregnant or planning to become pregnant whilst taking this medicine.

Like most medicines of this kind, ORDINE oral solution is not recommended to be used during pregnancy. Your doctor will discuss the risks of taking it if you are pregnant.

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

Do not give this medicine to a child under one year of age including premature infants.

Safety and efficacy in children less than one year of age 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:

- low blood pressure
- increased prostate size or difficulty passing urine
- problems with your gall bladder or bile duct
- inflammation of the pancreas
- chronic lung, liver or kidney disease
- underactive adrenal glands
- underactive thyroid gland
- inflammatory bowel disease or recent abdominal surgery
- are about to have an operation or have just had one within the last 24 hours
- an addiction or history of abuse of alcohol or drugs.

This medicine is not recommended to be taken during labour.

Morphine given to the mother during labour may cause breathing problems and signs of withdrawal in the newborn.

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

Morphine can pass into the breast milk and can affect the baby. Your doctor can discuss with you the risks involved.

If you have not told your doctor about any of the above, tell them before you start taking ORDINE oral solution.

Taking other medicines

Tell your doctor if you are taking any other medicines or dietary supplements, including any that

you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ORDINE oral solution may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders
- medicines to treat depression belonging to a group called 'monoamine oxidase inhibitors' must be stopped 14 days before ORDINE oral solution is taken
- medicines to help you sleep, including medicines belonging to a group called 'benzodiazepines'
- medicines to put you to sleep during an operation or procedure
- medicines to relax your muscles
- medicines to prevent or relieve the symptoms of allergy such as antihistamines
- propranolol or other medicines to lower blood pressure
- gabapentin or barbiturates, medicines to treat seizures
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- medicines used to relieve heartburn or treat stomach ulcers such as cimetidine or antacids
- medicines to treat Parkinson's disease
- medicines to stop nausea and vomiting e.g. metoclopramide or prochlorperazine
- rifampicin, a medicine to treat tuberculosis
- other pain relievers including other opioids
- medicines to treat HIV infection and AIDs e.g. ritonavir or zidovudine
- alcohol.

These medicines and alcohol may be affected by ORDINE oral solution, may affect how well ORDINE oral solution works 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 ORDINE oral solution

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 on the bottle, ask your doctor or pharmacist for help.

How to take it

Measure the dose accurately with a medicine measure.

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 your pharmacist. Wipe the neck of the bottle and the cap after use to assist with re-opening.

This medicine only lasts for 6 months once the bottle has been opened as long as the expiry date has not passed. Discard any remaining solution after the 6 months has passed.

To help you remember, write the date you open the bottle on the label and check the expiry date.

You must only take ORDINE oral solution by mouth.

ORDINE oral solution is only designed to work properly if taken by mouth. Taking this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

When to take it

Take ORDINE oral solution every four hours, or as directed by your doctor, to control the pain. If your doctor has told you to take it routinely, take the doses at about the same time each day.

If you begin to experience pain and you are taking ORDINE oral solution as prescribed, contact your doctor as your dosage may have to be reviewed.

You can take this medicine before or after food.

If you are already taking other medications for your pain, your doctor may have recommended that you also take ORDINE oral solution as required for the relief of breakthrough pain.

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, stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness.

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 that you missed.

This will increase the chance of you getting unwanted side effects.

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

For example, take your medicine at the same times each day.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ORDINE oral solution.

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

You may need urgent medical attention.

Keep telephone numbers for these places handy.

You should also follow the above steps if someone other than you has accidentally taken ORDINE oral solution that was prescribed for you.

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

When seeking medical attention, take this leaflet and the bottle 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 ORDINE oral solution exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and pharmacist that you are taking ORDINE oral solution.

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 and 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 your doctor's appointments so that your progress can be checked.

Tell your doctor if your pain is getting worse. Also tell your doctor if you are having any problems or difficulties while you are being treated with ORDINE oral solution.

Tolerance to morphine may develop which means that the effect of the medicine may decrease. If this happens, speak to your doctor.

Keep enough ORDINE oral solution with you to last over weekends and holidays.

Things you must not do

Do not drink alcohol while you are taking ORDINE oral solution.

Drinking alcohol whilst taking ORDINE oral solution may make you feel more sleepy and increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Do not take ORDINE oral solution to treat any other complaint unless your doctor tells you to.

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

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

Over time your body may become used to you taking morphine. If you stop taking it suddenly, your pain may worsen and you may experience 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.

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 your dose is increased.

This feeling should wear off after a few days.

Do not drive or operate machinery until you know how ORDINE oral solution affects you.

ORDINE oral solution may cause drowsiness, dizziness, hallucinations, confusion, vision problems or may affect alertness. If you are affected, you should not drive or operate machinery. Discuss these effects 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.

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.

Tell your doctor if you suffer from nausea or vomiting when taking ORDINE oral solution.

If you vomit after taking your dose, your pain may come back as you may not have absorbed your morphine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help stop vomiting.

Tell your doctor if taking ORDINE oral solution causes constipation.

Your doctor can advise you about your diet, the proper use of laxatives or alternative treatments and suitable exercise you can do to help manage this.

There is potential for abuse of morphine and the development of addiction to morphine. 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 using 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 or pharmacist as soon as possible if you do not feel well while you are taking ORDINE oral solution.

This medicine helps most people with 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 symptoms and they worry you:

- mild abdominal problems such as feeling sick (nausea), loss of appetite or constipation
- dry mouth or changes in taste
- sweating
- facial flushing
- trouble sleeping
- trouble with your balance
- new problems with your eyesight
- skin rash or itching

- absence of menstrual periods
- sexual problems
- muscle twitching or muscle stiffness
- swelling, including but not only of the legs or ankles.

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
- abnormal thinking or changes in mood
- drowsiness, feeling faint or fainting or dizziness especially when standing up
- slow or noticeable heartbeats
- headache, confusion or hallucinations
- unusual weakness or loss of strength
- changes in passing urine, such as the volume passed, pain or feeling the need to urinate urgently.

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

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 face, lips, tongue, throat 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 solution with you to show the doctor.

After taking it

Storage

Keep your ORDINE oral solution in the bottle with the lid tightly fastened until it is time to take it.

If you take the solution out of the bottle or leave the lid off it may not keep well.

Keep your medicine in a cool dry place, away from light, where the temperature stays below 30°C.

Do not store it in the refrigerator.

Do not store it or any other medicine in the bathroom, near a sink or leave it 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

ORDINE oral solution only lasts for 6 months once the bottle has been opened as long as the expiry date has not passed. Discard any remaining solution once the 6 months has passed.

To help you remember, write the date of opening on the label.

If your doctor tells you to stop taking this medicine or the expiry date has passed, return any unused medicine to your pharmacist.

Product description

What it looks like

ORDINE® oral solution is a clear, colourless or pale yellow aqueous solution in a 200 mL brown plastic bottle.

ORDINE® oral solution is available in 4 strengths:

1 mg/mL

2 mg/mL

5 mg/mL

10 mg/mL

Ingredients

Active ingredient:

One mL of solution contains the following:

- 1 mg morphine hydrochloride trihydrate in the 1 mg/mL solution
- 2 mg morphine hydrochloride trihydrate in the 2 mg/mL solution
- 5 mg morphine hydrochloride trihydrate in the 5 mg/mL solution
- 10 mg morphine trihydrate hydrochloride in the 10 mg/mL solution.

Inactive ingredients:

- anhydrous citric acid
- sodium citrate
- glycerol
- disodium edetate
- sodium methyl hydroxybenzoate (preservative)
- water for injections.

ORDINE® oral solution does not contain sugar, alcohol, gluten, lactose, tartrazine or azo dyes.

Manufacturer / Sponsor

ORDINE® oral solution is made in Australia and distributed by:

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

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2 mg/mL: AUST R 150220

5 mg/mL: AUST R 150221

10 mg/mL: AUST R 150222

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