Mayne Pharma Oxycodone IR Tablets

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I taking Mayne Pharma Oxycodone IR Tablets?

Mayne Pharma Oxycodone IR Tablets contain the active ingredient oxycodone hydrochloride. Mayne Pharma Oxycodone IR Tablets are used for the short-term management of severe pain. For more information, see Section 1. Why am I taking Mayne Pharma Oxycodone IR Tablets? in the full CMI.

2. What should I know before I take Mayne Pharma Oxycodone IR Tablets?

Do not take if you have ever had an allergic reaction to oxycodone or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other**

medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I take Mayne Pharma Oxycodone IR Tablets? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mayne Pharma Oxycodone IR Tablets and affect how they work. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Mayne Pharma Oxycodone IR Tablets?

The usual dose is one tablet every six hours. Your doctor may prescribe a different dose for you. Be sure to follow your doctor's directions about when and how to take Mayne Pharma Oxycodone IR Tablets. Swallow the tablet whole with a full glass of water preferably after food or with milk. More instructions can be found in Section 4. How do I take Mayne Pharma Oxycodone IR Tablets? in the full CMI.

5. What should I know while taking Mayne Pharma Oxycodone IR Tablets?

Things you should do	• If you are going to have surgery, tell the surgeon

	or anaesthetist that you are taking this medicine. • Remind any doctor, dentist or pharmacist you visit that you are taking this medicine. • 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.
Things you should not do	• Do not take this medicine to treat any other complaints 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 or lower the dosage without checking with your doctor.
Driving or using machines	• Do not drive or operate machinery until you

	know how this medicine affects you.
Drinking alcohol	• Do not drink alcohol while you are taking this medicine.
Looking after your medicine	• Keep your tablets in the pack until it is time to take them. • Keep your tablets in a cool dry place where the temperature stays below 25°C. • Keep them where children cannot reach them.

For more information, see Section 5. What should I know while taking Mayne Pharma Oxycodone IR Tablets? in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of these: dizziness, light-headedness and confusion; drowsiness; nausea. **Call your doctor as soon as possible if you notice any of these:** difficulty passing urine; dry mouth; irregular heart beat; decrease in body temperature; hallucinations; muscle rigidity; severe headache due to increased pressure in the head. **Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice**

any of these: loss of consciousness; difficulty or an inability to breathe properly; severe dizziness, drowsiness or disorientation; symptoms of an allergic reaction (itchy skin rash, skin blisters or discolouration of skin upon exposure to sunlight). **This is not a complete list of all possible side effects.** For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING

Limitations of use

Mayne Pharma Oxycodone IR Tablets should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

Mayne Pharma Oxycodone IR Tablets pose risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Mayne Pharma Oxycodone IR Tablets can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Mayne Pharma Oxycodone IR Tablets and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while taking Mayne Pharma Oxycodone IR Tablets

Using Mayne Pharma Oxycodone IR Tablets with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics,

gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death.

Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while taking Mayne Pharma Oxycodone IR Tablets.

Mayne Pharma Oxycodone IR Tablets

Active ingredient(s): oxycodone hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mayne Pharma Oxycodone IR Tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Mayne Pharma Oxycodone IR Tablets.**

Where to find information in this leaflet:

1. Why am I taking Mayne Pharma Oxycodone IR Tablets?

2. What should I know before I take Mayne Pharma Oxycodone IR Tablets?

3. What if I am taking other medicines?

4. How do I take Mayne Pharma Oxycodone IR Tablets?

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5. What should I know while taking Mayne Pharma Oxycodone IR Tablets?

6. Are there any side effects?

7. Product details

1. Why am I taking Mayne Pharma Oxycodone IR Tablets?

Mayne Pharma Oxycodone IR Tablets contain the active ingredient oxycodone hydrochloride. This medicine belongs to a group of medicines called narcotic analgesics.

Mayne Pharma Oxycodone IR Tablets are used for the short-term management of severe pain.

The active ingredient in this medicine works by binding to receptors called opioid receptors, which are in your central nervous system. This binding action changes your body's perception of pain throughout the central nervous system producing the pain relieving (analgesic) effect.

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

Your doctor may have prescribed it for another reason.

2. What should I know before I take Mayne Pharma Oxycodone IR Tablets?

Addiction

You can become addicted to Mayne Pharma Oxycodone IR Tablets even if you take them exactly as prescribed. This medicine may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking this medicine. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Mayne Pharma Oxycodone IR Tablets suddenly, so it is important to take the product exactly as directed by your doctor.

Tolerance

Tolerance to Mayne Pharma Oxycodone IR Tablets may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect. Speak to your doctor if this occurs.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea

- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Mayne Pharma Oxycodone IR Tablets given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Warnings

Do not use Mayne Pharma Oxycodone IR Tablets if:

- you have an allergy to you have any allergy to any medicine containing oxycodone hydrochloride, any other narcotic analgesics such as morphine, codeine or opium or any of the ingredients listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin

  Always check the ingredients to make sure you can take this medicine.
- you have or have had any of the following:
  - head injury
  - brain tumour
  - epilepsy or other convulsive disorders

- heart problems such as an irregular and/or rapid heartbeat
- chronic obstructive pulmonary disease, asthma or other respiratory diseases
- severe headaches, or headaches due to raised pressure in the head
- a history of alcohol or drug abuse
- a history of mental illness

- you are pregnant
- you are breastfeeding
- you are taking or have taken medicines for depression called Monoamine Oxidase Inhibitors (MAOs) within
- the last 14 days.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

  If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be taking this medicine, consult your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- currently have or have had any of the following medical conditions:
  - muscle weakness
  - underactive thyroid
  - kidney disease

- liver disease
- low blood pressure
- prostate problems, or difficulty passing urine
- bowel disorders
- inflammation of the pancreas (which may cause severe pain in the abdomen and back)
- problems with your gall bladder or bile duct
- abdominal pain or discomfort (associated with colic)
- adrenal gland disorders
- sleep apnoea (breathing stops and starts while you sleep)
- prescription or illicit drug addiction

- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take Mayne Pharma Oxycodone IR Tablets if you are pregnant.

They may affect your developing baby if you take them during pregnancy.

Check with your doctor if you are pregnant or intend to become pregnant.

Do not breast-feed if you are taking Mayne Pharma Oxycodone IR Tablets.

The active ingredient in Mayne Pharma Oxycodone IR Tablets passes into breast milk and there is a possibility that your baby may be affected.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

If you have not told your doctor about any of the above, tell them before you start taking Mayne Pharma Oxycodone IR Tablets.

3. What if I am taking other medicines?

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

Some medicines and Mayne Pharma Oxycodone IR Tablets may interfere with each other. These include:

- anaesthetics
- anticoagulants, medicines used to thin the blood
- medicines used to treat epilepsy
- medicines used to help with sleeping
- medicines used to help lower blood pressure
- medicines used to treat anxiety

- medicines used to treat depression
- medicines used to treat cold and flu symptoms
- other medicines used to relieve pain
- medicines, used to relieve nausea and vomiting
- atropine-like medicines, used to prevent travel sickness and for stomach cramps and spasms
- medicines used to treat chronic obstructive pulmonary disorder
- antipsychotic medicines, used to treat psychosis, schizophrenia or bipolar disorder
- antihistamine medicines, used to treat allergic skin conditions or hay fever
- any medicine containing naloxone and/or naltrexone, used to reverse the effects of narcotic analgesics.

These medicines may be affected by Mayne Pharma Oxycodone IR Tablets or may affect how well they work. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mayne Pharma Oxycodone IR Tablets.

4. How do I take Mayne Pharma Oxycodone IR Tablets?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

- The usual dose is one tablet every six hours.
- Your doctor may prescribe a different dose for you. Be sure to follow your doctor's directions about when and how to take Mayne Pharma Oxycodone IR Tablets.

When to take Mayne Pharma Oxycodone IR Tablets

- Take the medicine at about the same time each day.

  Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- The medicine should be taken after food or with milk.

How to take Mayne Pharma Oxycodone IR Tablets

- Swallow the tablet whole with a full glass of water.

How long to take Mayne Pharma Oxycodone IR Tablets

- Continue taking your medicine for as long as yourdoctor tells you
- If you have been taking this medicine for a long period of time and it is no longer needed to manage your pain, **DO NOT stop taking Mayne Pharma Oxycodone IR Tablets suddenly**.

  Your doctor may want you to gradually reduce the amount of Mayne Pharma Oxycodone IR Tablets you are taking before stopping completely in order to lessen the risk of withdrawal symptoms

If you forget to take Mayne Pharma Oxycodone IR Tablets

If you miss your dose at the usual time and it is less than 3 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too many Mayne Pharma Oxycodone IR Tablets (overdose)

If you or someone else receives too much (overdoses), and experiences one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you has accidentally used Mayne Pharma Oxycodone IR Tablets that were prescribed for you.

If someone has an overdose, they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits
- clumsiness or loss of coordination
- difficulty walking
- facial drooping
- loss of vision
- personality changes
- trouble speaking

- weak muscles

If you think you or someone else may have taken too many Mayne Pharma Oxycodone IR Tablets urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while taking Mayne Pharma Oxycodone IR Tablets?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Mayne Pharma Oxycodone IR Tablets.
- Remind any doctor, dentist or pharmacist you visit that you are taking Mayne Pharma Oxycodone IR Tablets.

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

Call your doctor straight away if you:

- become pregnant while taking this medicine.
- experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

Things you should not do

- Do not take Mayne Pharma Oxycodone IR Tablets to treat any other complaints 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 or lower the dosage without checking with your doctor.

  If you stop taking it suddenly, you may have unwanted side effects, or you may experience withdrawal symptoms. Your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Driving or using machines

Do not drive or operate machinery until you know how Mayne Pharma Oxycodone IR Tablets affect you.

This medicine may impair the mental and physical ability needed to drive a car or operate heavy machinery.
It may cause drowsiness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous**.**

Drinking alcohol

Do not drink alcohol while you are taking this medicine.

Things to be careful of

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

Standing up slowly, especially when you get up from bed or chairs, 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.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.

  If you take the tablets out of the pack, they may not keep well.

- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on a windowsill.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mayne Pharma Oxycodone IR Tablets.

This medicine helps most people with their pain, but it may have unwanted side effects in a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• dizzi • lightl • confu • drow • cons • vomi • naus • dry mout • swea • redn of the face • unus tiredn or weak	**Speak to your doctor if you have any of these less serious side effects and they worry you.** This list includes

ness,

Less serious side effects	What to do
• sleep apno (brea stops and starts while you sleep • sexu dysfu • abse of mens perio	the more common side effects of your medicine.

Serious side effects

Serious side effects	What to do
• diffic pass urine • decre frequ	**Call your doctor as soon**

Serious side effects	What to do
of pass urine • loss of appe • diffic swall • fainti or feelir weak • slow, abno or fast hear rate • irregu hear • ches pain • feelir light when stanc up or	**as possible if you notice any of these serious side effects.** This list includes serious side effects that may require medical attention.

Serious side effects	What to do
wher getti out of bed • decr in body temp • restl or nerv • chan in mood • cons of pupil • hallu • musc rigidi • seve head due to incre press in	s s

Serious side effects	What to do
the head • seve uppe abdo pain poss radia to the back	

Very serious side effects

Serious side effects	What to do
• loss of cons • diffic or an inabi to brea prop	**Call your doctor** ss **straight away or go straight to the Emergency Department**

Serious side effects	What to do
• seve dizzi drow or disor • symp of an aller react (e.g. itchy skin rash, skin bliste or disco of skin upon expo to sunli	**at your nearest hospital if you notice any of these very serious side effects.** This list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

In long term use, physical dependence and tolerance to the medicine may develop. The following withdrawal symptoms may be experienced after stopping treatment with Mayne Pharma Oxycodone IR Tablets:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Mayne Pharma Oxycodone IR Tablets contain

Active ingredient **(main ingredient)**	• oxycodone hydrochloride
Other ingredients **(inactive ingredients)**	• Lactose monohydrate • Microcrystalline cellulose • Maize starch • Sodium starch glycollate type A • Stearic acid • Silicon dioxide
Potential allergens	This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes

Do not take this medicine if you are allergic to any of these ingredients.

What Mayne Pharma Oxycodone IR Tablets look like

Mayne Pharma Oxycodone IR Tablets are white to off-white, round tablets. One side is plain, the other side has a visible line and the number “112” debossed above it.

The tablets come in packs of 10 and 20 (Aust R 225335).

Who distributes Mayne Pharma Oxycodone IR Tablets

Mayne Pharma International Pty Ltd

1538 Main North Road

Salisbury South SA, 5106

maynepharma.com

This leaflet was prepared in October 2025.