

# Mayne Pharma Oxycodone IR Tablets

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## 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 using Mayne Pharma Oxycodone IR Tablets?

Mayne Pharma Oxycodone IR Tablets contain the active ingredient oxycodone hydrochloride. Oxycodone tablets are used to relieve pain where other treatment options are not able to effectively manage your pain or you cannot tolerate them. For more information, see Section [1. Why am I using Mayne Pharma Oxycodone IR Tablets?](#) in the full CMI.

## **2. What should I know before I use Mayne Pharma Oxycodone IR Tablets?**

Do not use 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 use Mayne Pharma Oxycodone IR Tablets?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Some medicines may interfere with oxycodone and affect how the tablets 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 use Mayne Pharma Oxycodone IR Tablets?**

The usual dose is ONE tablet every six hours. Swallow the tablet whole with a full glass of water. More instructions can be found in Section [4. How do I use Mayne Pharma Oxycodone IR Tablets?](#) in the full CMI.

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are using oxycodone.</li><li>● If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li><li>● If you become pregnant while taking this medicine, tell your doctor immediately.</li><li>● If you are about to have any blood tests, tell your doctor that you are taking this medicine.</li><li>● Keep all of your doctor's appointments so that your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not take oxycodone to treat any other complaints unless your doctor tells you to.</li><li>● Do not give your medicine to anyone else, even if they have</li></ul>

	<p>the same condition as you.</p> <ul style="list-style-type: none"> <li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li> <li>• Do not stop using this medicine suddenly.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how oxycodone affects you.</li> <li>• This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. It may affect alertness.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Do not drink alcohol while you are taking this medicine.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the pack until it is time to take them.</li> <li>• Keep your tablets in a cool dry place where the temperature stays below 25°C.</li> <li>• Do not store oxycodone or any other medicine in</li> </ul>

the bathroom or near a sink. Do not leave it on a windowsill or in the car. Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using oxycodone?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects: dizziness, confusion, drowsiness, low blood pressure, constipation, vomiting and nausea. Serious side effects: difficulty or decreased frequency of passing urine, dry mouth, sweating, itchy rash, muscle stiffness, face redness, loss of appetite, faintness or feeling weak, abnormal or changes in heart rate, fall in blood pressure on standing, decrease in body temperature, restlessness, severe headache, changes of mood, constriction of pupils, unconsciousness, difficulty breathing, severe dizziness, drowsiness or disorientation and symptoms of allergy. 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 using 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 using Mayne Pharma Oxycodone IR Tablets.

## Mayne Pharma Oxycodone IR Tablets

**Active ingredient(s):** oxycodone hydrochloride

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### 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 using Mayne Pharma Oxycodone IR Tablets.**

**Where to find information in this leaflet:**

- [1. Why am I using Mayne Pharma Oxycodone IR Tablets?](#)
- [2. What should I know before I use Mayne Pharma Oxycodone IR Tablets?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Mayne Pharma Oxycodone IR Tablets?](#)

[5. What should I know while using Mayne Pharma Oxycodone IR Tablets?](#)

[6. Are there any side effects?](#)

## **1. Why am I using Mayne Pharma Oxycodone IR Tablets?**

**Mayne Pharma Oxycodone IR Tablets contain the active ingredient oxycodone hydrochloride.**

Oxycodone belongs to a group of medicines called narcotic analgesics. Narcotic analgesics.

**Mayne Pharma Oxycodone IR Tablets are used to relieve pain where other treatment options are not able to effectively manage your pain or you cannot tolerate them.**

**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.

Oxycodone can be addictive. If used for a long time Oxycodone may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Oxycodone is available only with a doctor's prescription.

## **2. What should I know before I use Mayne Pharma Oxycodone IR Tablets?**

### **Warnings**

#### **Do not use Mayne Pharma Oxycodone IR Tablets if:**

- you have an allergy to:
  - any medicine containing oxycodone hydrochloride  
any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can  
use this medicine
- any other similar medicines known as narcotic  
analgesics e.g. morphine, codeine, opium.  
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

#### **Check with your doctor if you:**

- have allergies to any other medicines, foods,  
preservatives or dyes.

- have any other medical conditions, in particular:
  - muscle weakness
  - underactive thyroid
  - kidney disease
  - liver disease
  - low blood pressure
  - if a male, prostate problems or difficulty passing urine
  - bowel disorders

It may not be safe for you to take oxycodone if you have these conditions. Your doctor will need to consider all these factors when advising you about taking oxycodone.

- 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**

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

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

### 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 oxycodone may interfere with each other. These include:

- anaesthetics
- medicines used to thin the blood
- medicines used to treat epilepsy
- medicines used to help with sleeping
- blood pressure lowering medicines
- medicines used to treat mental health problems
- medicines used to treat anxiety or depression
- medicines used to treat 'flu' symptoms
- pain relievers
- medicines used to relieve stomach cramps or spasms
- (example) warfarin, a medicine used to prevent blood clots

**These medicines and alcohol may be affected by oxycodone or may affect how well it works.**

You may need different amounts of your medicines, or you may need to take different medicines.

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.

**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 use Mayne Pharma Oxycodone IR Tablets?**

### **How much to take**

- **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.**

- 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 oxycodone.
- The length of treatment will depend on your condition. Your doctor will advise you when to stop taking oxycodone tablets.

## **When to take Mayne Pharma Oxycodone IR Tablets**

- Oxycodone should be taken after meals or with milk.

## **How to take Mayne Pharma Oxycodone IR Tablets**

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

## **If you forget to take Mayne Pharma Oxycodone IR Tablets**

**If it is less than 2-3 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 that you missed.**

**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 takes too much oxycodone (overdoses), and experience 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

**If you think you or someone else may have taken too many Mayne Pharma Oxycodone IR Tablets 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 using 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 oxycodone.**
- **Remind any doctor, dentist or pharmacist you visit that you are using 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.**
- **If you become pregnant while taking this medicine, tell your doctor immediately.**
- **If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

### **Things you should not do**

- **Do not take oxycodone 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.
- Do not stop using this medicine suddenly. If you have been taking this medicine for a long period of time and stop taking it suddenly, you may have unwanted side effects such as withdrawal symptoms. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Mayne Pharma Oxycodone IR Tablets affect you.**

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. It may affect alertness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**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.

## **Drinking alcohol**

**Do not drink alcohol while you are taking this medicine.**

## **Hyperalgesia**

An unexplained increased sensitivity to pain may occur with the use of opioids at high doses. If this occurs, the dose should be reduced and a change to another medicine may be required.

## **Addiction**

You can become addicted to Mayne Pharma Oxycodone IR Tablets even if you take them exactly as prescribed. Oxycodone 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 oxycodone. 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.

## 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.

## 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 windowsills.

### **Keep medicines where children cannot reach them.**

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?**

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.

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

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

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• dizziness, light headedness, confusion</li> <li>• drowsiness</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● unusual tiredness or weakness</li> <li>● low blood pressure</li> <li>● constipation</li> <li>● vomiting</li> <li>● nausea</li> </ul>	

### **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● difficulty passing urine</li> <li>● decreased frequency of passing urine</li> <li>● dry mouth</li> <li>● sweating</li> <li>● itchy rash</li> <li>● muscle stiffness</li> <li>● redness of the face</li> <li>● loss of appetite</li> <li>● faintness or feeling weak</li> <li>● slow, abnormal or fast heart rate</li> <li>● fall in blood pressure on standing</li> <li>● decrease in body temperature</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● central nervous system stimulation and convulsions (especially in children)</li> <li>● physical and psychological tolerance</li> <li>● restlessness</li> <li>● severe headache due to increased pressure within the head</li> <li>● changes of mood</li> <li>● constriction of pupils</li> <li>● unconsciousness</li> <li>● inability to breathe properly</li> <li>● severe dizziness, drowsiness or disorientation</li> <li>● symptoms of allergy (e.g. itchy skin rash, skin blisters or discolouration of skin upon exposure to sunlight).</li> </ul>	

**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 may develop and the following withdrawal symptoms may be observed after oxycodone is discontinued:

- **body aches**
- **loose bowel motions or diarrhoea**
- **loss of appetite**
- **nervousness**
- **restlessness**
- **runny nose**
- **sneezing**
- **shivering**
- **stomach cramps**
- **nausea**
- **trouble with sleeping**
- **an increase in sweating and yawning**
- **weakness**
- **fast heart rate**
- **unexplained fever**

**These symptoms are mild if withdrawal from oxycodone is gradual once it is no longer needed.**

## **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](http://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**

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• oxycodone hydrochloride</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Lactose monohydrate</li><li>• Microcrystalline cellulose</li><li>• Maize starch</li><li>• Sodium starch glycollate type A</li><li>• Stearic acid</li><li>• Silicon dioxide</li></ul>
<b>Potential allergens</b>	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 is scored and debossed "112".

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

[www.maynepharma.com/products/australian-products/](http://www.maynepharma.com/products/australian-products/)

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