ENDONE®

Consumer Medicine Information (CMI) summary

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

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

1. Why am I taking ENDONE?

ENDONE contains the active ingredient oxycodone hydrochloride. ENDONE is used for the short-term management of severe pain. For more information, see Section 1. Why am I taking ENDONE? in the full CMI.

2. What should I know before I take ENDONE?

Do not take if you have ever had an allergic reaction to ENDONE 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 ENDONE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ENDONE and affect how it works. 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 ENDONE?

- 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 ENDONE.
- Swallow the tablets whole with a full glass of water after food or with milk.

More instructions can be found in Section 4. How do I take ENDONE? in the full CMI.

5. What should I know while taking ENDONE?

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 ENDONE. • If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	• Do not take ENDONE 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 first checking with your doctor.
Driving or using machines	• Do not drive or operate machinery until you know how ENDONE 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 30°C. • Keep it where young children cannot reach it.

For more information, see Section 5. What should I know while taking ENDONE? 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

ENDONE 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

ENDONE poses 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

ENDONE can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when taken as recommended. These problems can occur at any time during use, but the risk is higher when first starting ENDONE 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 ENDONE

Using ENDONE 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 ENDONE.

ENDONE®

Active ingredient(s): *oxycodone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ENDONE. **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 ENDONE.**

Where to find information in this leaflet:

1. Why am I taking ENDONE?
2. What should I know before I take ENDONE?
3. What if I am taking other medicines?
4. How do I take ENDONE?
5. What should I know while taking ENDONE?
6. Are there any side effects?
7. Product details

1. Why am I taking ENDONE?

ENDONE contains the active ingredient oxycodone hydrochloride. This medicine belongs to a group of medicines called narcotic analgesics.

ENDONE is 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.

Addiction

You can become addicted to ENDONE even if you take it exactly as prescribed. ENDONE 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 ENDONE. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking ENDONE suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to ENDONE 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 taking 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

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

2. What should I know before I take ENDONE?

Warnings

Do not take ENDONE if:

- 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:
    - o shortness of breath
    - o wheezing or difficulty breathing
    - o swelling of the face, lips, tongue or other parts of the body
    - o 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:
    - o head injury
    - o brain tumour
    - o epilepsy or other convulsive disorders
    - o heart problems such as an irregular and/or rapid heartbeat
    - o chronic obstructive pulmonary disease, asthma or other respiratory diseases
    - o severe headaches, or headaches due to raised pressure in the head
    - o a history of alcohol or drug abuse
    - o 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:
    - o muscle weakness
    - o underactive thyroid
    - o kidney disease
    - o liver disease
    - o low blood pressure
    - o prostate problems, or difficulty in passing urine
    - o bowel disorders
    - o inflammation of the pancreas (which may cause severe pain in the abdomen and back)
    - o problems with your gall bladder or bile duct
    - o abdominal pain or discomfort (associated with colic)
    - o adrenal gland disorders
    - o sleep apnoea (breathing stops and starts while you sleep)
    - o 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 ENDONE if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

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

Do not breast-feed if you are taking ENDONE.

The active ingredient in ENDONE 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 ENDONE.

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 ENDONE 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 ENDONE or may affect how well it works. 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 ENDONE.

4. How do I take ENDONE?

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 ENDONE.

When to take ENDONE

- Take ENDONE 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.
- ENDONE should be taken after food or with milk.

How to take ENDONE

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

How long to take ENDONE

- Continue taking your medicine for as long as your doctor 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 ENDONE suddenly**.

  Your doctor may want you to gradually reduce the amount of ENDONE you are taking before stopping completely in order to lessen the risk of withdrawal symptoms.

If you forget to take ENDONE

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 much ENDONE

If you or someone else receives too much (overdose), 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 have accidentally taken ENDONE that was prescribed for you.

If someone takes 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

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If you think you or someone else have taken too much ENDONE, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 any 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 ENDONE?

Things you should do

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

- **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 ENDONE 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 first checking with your doctor.

  If you stop taking it suddenly, your condition may worsen, 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 this medicine completely.

Driving or using machines

Do not drive or operate machinery until you know how ENDONE affects 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. Tell your doctor if you drink alcohol.

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 30°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 window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

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

Do not take 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 ENDONE.

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
• dizziness, light-headedness, and confusion • drowsiness • constipation • vomiting • nausea • dry mouth • sweating • redness of the face • unusual tiredness or weakness • sleep apnoea (breathing stops and starts while you sleep) • sexual dysfunction • absence of menstrual period	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• difficulty passing urine • decreased frequency of passing urine • loss of appetite • difficulty swallowing • fainting or feeling weak • slow heart rate • abnormal and fast heart rate • irregular heart beat	**Call your doctor as soon as possible if you notice any of these serious side effects.** This list includes serious side effects that

Serious side effects	What to do
• chest pain • feeling light headed when standing up or when getting out of bed • decrease in body temperature • restlessness or nervousness • changes in mood • constriction of pupils • hallucinations • muscle rigidity • severe headache due to increased pressure in the head • severe upper abdominal pain possibly radiating to the back.	may require medical attention.

Very serious side effects

Very serious side effects	What to do
• 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)	**Call your doctor straight away or go straight to the Emergency Department 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 ENDONE:

- 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 ENDONE contains

Active ingredient (main ingredient)	5 mg of oxycodone hydrochloride per tablet
Other ingredients (inactive ingredients)	• lactose • microcrystalline cellulose • stearic acid
Potential allergens	sugars as lactose

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

What ENDONE looks like

ENDONE is a white, round, biconvex 10 mm tablet, one side embossed "O 5" with a break bar on the other side (AUST R 14945).

Available in blister packs of 20 tablets.

Sponsor

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