

ENDONE®

oxycodone hydrochloride

Consumer Medicine Information

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 used 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 using 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 using ENDONE.

What is in this leaflet

This leaflet answers some common questions about ENDONE. 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 ENDONE 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 want to read it again.

What ENDONE is used for

This medicine is used for the short-term management of severe pain.

This medicine belongs to a group of medicines called narcotic analgesics.

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.

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

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.

Before you take ENDONE

When you must not take it

Do not take ENDONE if you have an allergy to:

- any medicine containing oxycodone hydrochloride
- any other narcotic analgesics such as morphine, codeine, or opium
- 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

Do not take this medicine if you are pregnant.

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

Do not breast-feed if you are taking this medicine.

The active ingredient in ENDONE passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

Do not take this medicine if 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

Do not take this medicine if you are taking or have taken medicines for depression called Monoamine Oxidase Inhibitors (MAOs) within the last 14 days.

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

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 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 in passing urine
- bowel disorders
- prescription or illicit drug addiction

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

Taking other medicines

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

Some medicines 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.

How to 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.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your 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.

ENDONE should be taken after food or with milk.

How long to take it

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

If you have been using 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 it

If 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 that 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 (overdose)

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 used 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

If you think you or someone else may have used too much ENDONE, 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 any remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

While you are using ENDONE

Things you must do

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

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.

Things you must 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.

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.

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.

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness, light-headedness, and confusion
- drowsiness
- constipation
- vomiting
- nausea
- unusual tiredness or weakness

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- difficulty passing urine
- decreased frequency of passing urine
- dry mouth
- sweating
- redness of the face
- loss of appetite
- fainting or feeling weak
- slow heart rate
- abnormal and fast heart rate
- irregular heart beat

- 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

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:

- 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)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also 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

After using ENDONE

Storage

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 as well.

Keep your tablets in a cool, dry place where the temperature stays below 30°C.

Do not store ENDONE or any other medication in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can ruin some medicines.

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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ENDONE is available in blister packs of 20 tablets.

ENDONE tablets are white and round tablets, with one side embossed "O 5" and a break bar on the other side.

Ingredients

ENDONE contains 5 mg of oxycodone (as oxycodone hydrochloride) as the active ingredient.

The tablets also contain the following inactive ingredients:

- lactose
- microcrystalline cellulose
- stearic acid

ENDONE contains sugars as lactose.

Distributor

ENDONE is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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ENDONE® is a Viatris company trade mark

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