

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions asked about ENDONE. It does not contain all the available information about this medicine. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine. You may want to read it again later.

What ENDONE is used for

This medicine contains oxycodone hydrochloride.

ENDONE belongs to a group of medicines called narcotic analgesics. Narcotic analgesics act to relieve pain.

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

Your doctor may prescribe ENDONE for another reason.

ENDONE is only available with a doctor's prescription.

WARNING:

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

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 of the ingredients listed at the end of this leaflet
- any other similar medicine known as narcotic analgesics, eg. morphine, codeine, opium.

Some of the symptoms of an allergic reaction may be an itchy skin rash, skin blisters or discolouration of the skin upon exposure to sunlight.

Do not use ENDONE if you currently have or have had any of the following:

- head injury
- brain tumour
- alcoholism
- epilepsy (also known as fitting)
- are taking or have taken in the last 14 days medicines for depression called Monoamine Oxidase Inhibitors (MAOIs).
- heart problems such as an irregular and/or rapid heartbeat
- asthma
- any difficulty breathing
- depression
- severe headaches due to raised pressure in the head

Your doctor will need to know about all of these before prescribing ENDONE for you.

Do not take ENDONE during pregnancy or during breastfeeding as it may cause difficulty in breathing in an unborn or newborn child.

Women who are pregnant, planning to become pregnant or who are breastfeeding should discuss this with their doctor.

Do not give this medicine to children.

There is not enough information available to recommend the use of ENDONE in children.

Do not take ENDONE after the expiry date (EXP) printed on the packet or if the packaging is torn or shows signs of tampering.

It may not work as well if you take it after the expiry date. Return it to your pharmacist for disposal.

If you are not sure whether you should be taking ENDONE, 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 health problems/medical conditions.

- muscle weakness
- underactive thyroid
- kidney disease
- liver disease
- low blood pressure
- if a male, prostate problems or difficulty passing water
- bowel disorders

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

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

Taking other medicines

You must tell your doctor about all the medicines you are taking, including any that you may buy from pharmacies, health food shops or supermarkets.

Some medicines may interfere with ENDONE and 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 problems
- medicines used to reduce anxiety
- medicines used to treat depression
- medicines used to treat “flu” symptoms
- pain relievers
- medicines used to relieve stomach cramps or spasms

These medicines and alcohol may be affected by ENDONE or they may affect how well ENDONE works. You may need to take different amounts of these medicines, or you may need to take different medicines.

Your doctor or pharmacist has a more complete list of medicines to avoid while taking ENDONE.

If you have not told your doctor about any of the above, tell him/her before you take ENDONE.

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 bottle, 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 ENDONE with a full glass of water.

ENDONE should be taken after meals or with milk.

How long to take it

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

If you have been using ENDONE for a long period of time and it is no longer needed to control pain DO NOT suddenly stop taking ENDONE. 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 you forget to take a dose of ENDONE, take the dose as soon as you remember and then go back to taking it as you would normally. However, if it is almost time for your next dose, for example within 2 or 3 hours, skip the missed dose and take the next dose when you are meant to.

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 when to take ENDONE, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Casualty Department at your nearest hospital, if you think that you or anyone else may have taken too much ENDONE, even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for your doctor, the Poisons Information Centre and your nearest hospital handy so that they are accessible in case of an emergency.

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

If you take an overdose of ENDONE you may start feeling sleepy and may experience difficulty in breathing which could lead to unconsciousness and loss of muscle control. Your heart may stop and death may occur.

While you are using ENDONE

Things you must do

Tell all other doctors, dentists and pharmacists who are treating you that you are taking ENDONE.

Remind them that you are taking ENDONE if you are about to be started on any new medicine or before you have any kind of surgery.

Tell your doctor if you become pregnant while taking ENDONE.

Things you must not do

Do not take any other medicines while you are taking ENDONE unless you have discussed this with your doctor.

This includes medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Do not take ENDONE to treat any complaint other than that directed by your doctor.

It may not be safe to take ENDONE for another complaint.

Do not give ENDONE to anyone else, even if their symptoms seem similar.

It may not be safe for another person to take ENDONE.

Do not stop taking ENDONE or lower or increase the dose without first checking with your doctor.

If you stop taking it suddenly, your pain may come back and you may experience some symptoms of withdrawal.

Do not let yourself run out of medicine over the weekend or on holidays.

Things to be careful of

Be careful when drinking alcohol while you are taking ENDONE.

The combination could make you more dizzy, sleepy or light-headed than usual. Your doctor may suggest you avoid alcohol while you are taking ENDONE.

Be careful driving or operating machinery until you know how ENDONE affects you.

ENDONE may cause drowsiness, sleepiness or dizziness in some people and affect alertness. Make sure you know how you react to ENDONE before you drive or operate machinery.

People over 65 years have a higher risk of getting side effects from medicines.

Families and carers should be aware that these people might become confused while taking ENDONE. Special care may be needed.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ENDONE even if you do not think the problems are connected with the medication or they are not listed in this leaflet.

All medicines can have side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and require medical attention.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- dizziness, light-headedness, and confusion
- drowsiness
- hypotension
- constipation
- vomiting

- nausea

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
- faintness or feeling weak
- slow heart rate
- abnormal and fast heart rate
- irregular heart beat
- fall in blood pressure on standing
- decrease in body temperature
- restlessness
- changes of mood
- constriction of pupils

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

If any of the following occur, tell your doctor immediately or go to accident and emergency at your nearest hospital:

- unconsciousness
- inability to breathe properly
- severe dizziness, drowsiness or disorientation
- symptoms of allergy (eg. itchy skin rash, skin blisters or discolouration of skin upon exposure to sunlight)

These are uncommon but serious side effects. Urgent medical attention may be required to deal with these effects.

Some of the less common side effects are:

- muscle stiffness
- itchy rash or other forms of itchiness
- severe headache due to increased pressure within the head

High doses of ENDONE can cause:

- unconsciousness
- heart failure
- low blood pressure

- inability to breath properly

In long term use, physical dependence and tolerance may develop and the following withdrawal symptoms may be observed after ENDONE is discontinued:

- body aches
- loose bowel motions or diarrhoea
- gooseflesh or goose bumps
- 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 ENDONE is gradual once it is no longer needed.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell while taking ENDONE.

Early consultation with your doctor can help prevent more serious complications by allowing prompt adjustments in your ENDONE therapy.

Storage

Keep ENDONE tablets in their container until it is time to take them.

If you take them out of their container, they may not keep well.

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

Do not store ENDONE tablets 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 (5 feet) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ENDONE or you find that they have passed their expiry date, ask your pharmacist what to do with any unused medicine.

Product Description

What it looks like

ENDONE is a white, scored uncoated tablet engraved with the word "ENDONE" on one side and break bar on the other side.

Ingredients

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

The other ingredients in ENDONE tablets are:

- lactose
- microcrystalline cellulose
- stearic acid

Sponsor

ENDONE is distributed in Australia by:

Sigma Pharmaceuticals (Australia)
Pty Ltd
(ACN 000 118 594)
96 Merrindale Drive
Croydon VIC 3136

The Australian Registration number for ENDONE 5 mg tablets is:
AUST R 14945

This leaflet was prepared in September 1996 and updated July 2009.