

OXYCONTIN® CONTROLLED-RELEASE TABLETS

Oxycodone hydrochloride (10mg, 20mg)

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What OxyContin® is used for

These tablets have been prescribed for you by your doctor to relieve moderate to severe pain that require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioids medicines do not treat your pain well enough or you cannot tolerate them.

A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Not for use to treat pain that is not around-the-clock.

How OxyContin® works

Oxycodone is a full opioid agonist with no antagonist properties. It has an affinity for kappa, mu and delta opiate receptors in the brain and spinal cord. Oxycodone is similar to morphine in its action.

The therapeutic effect is mainly analgesic, antianxiety and sedative.

Before you take OxyContin®

-When you must not use it

- Do not take OxyContin® tablets if
- are allergic (hypersensitive) to oxycodone
 - severe asthma, trouble breathing or other lung problems
 - a bowel blockage or have narrowing of the stomach or intestines

-Before you start take it

Before treatment with these tablets tell your doctor or pharmacist if you:

- have low blood pressure (hypotension) including from having low blood volume
- have head injury
- have liver or kidney problem
- have adrenal gland problems, such as Addison's disease
- have convulsions or seizures
- have alcoholism
- have hallucinations or other severe mental problems
- have past or present substance abuse or drug addiction

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Tell your doctor or pharmacist if you are taking:

- medicines to relax your muscles
- medicines to put you to sleep during an operation or procedure (general anaesthetics)
- medicines to help you sleep (for example tranquillisers, hypnotics or sedatives)
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- agents affecting Cytochrome P450 Isoenzymes (erythromycin, ketoconazole, ritonavir, carbamazepine, phenytoin)
- medicine to treat heart and blood vessels (such as quinine)
- medicine for antidepressant (such as fluoxetine)
- other strong analgesics or painkillers, including other opioids (such as pentazocine, nalbuphine and butorphanol)
- alcohol.

Taking OxyContin® with a benzodiazepine (medicine used as

sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepines.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

You should not use these tablets during pregnancy and labour unless you have been specifically told by your doctor.

Breastfeeding

These tablets should not be used while breastfeeding because the active ingredient can pass into breast milk.

How to use OxyContin®

-How much to use

Always take these tablets exactly as your doctor has told you. The label on your medicine will tell you how many tablets to take and how often.

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

OxyContin® tablets 80mg should only be used if you are tolerant to opioids. Swallow your tablets whole with a glass of water. Do not break, crush, dissolve or chew before swallowing. If the tablets are not whole, your body will absorb too much medicine at one time. This can lead to serious problems, including overdose and death.

You must only take the tablets by mouth. Take the tablets after meals.

-When to use it

Elderly and adults over 18 years of age

The usual starting dose is one 10 mg tablet every 12 hours for patients with severe pain uncontrolled by weaker opioids. However, your doctor will prescribe the dose required to treat your pain. If you find that you are still in

pain whilst taking these tablets, discuss this with your doctor.

Children

Children and adolescents under 18 years of age should not take the tablets.

-How long to use it

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

You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects.

- If you forget to use it

If you miss a dose, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once unless your doctor tells you to.

-If you use too much (overdose)

Call your doctor or hospital straight away. People who have taken an overdose may feel have breathing problems or breathlessness, drowsiness that leads to reduced consciousness or coma, reduced muscle tone, cold and cold sweat, develop pinpoint pupils, unusual or irregular snoring and death.

Abnormal dilation of the pupil of the eye could develop due to severe reduction of oxygen supply in overdose situations

An overdose may result in a brain disorder (known as toxic leukoencephalopathy).

While you are taking it

-Things you must do

Take OxyContin® tablets exactly as your doctor has prescribed. Before you start on a new medicine, remind your doctor and pharmacist that you are taking OxyContin® tablets. 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. Tell your doctor if your pain is getting worse or you are having more frequent breakthrough pain.

Also tell your doctor if you are having any problems or difficulties while you are being treated with OxyContin® tablets.

Tolerance to oxycodone may develop which means that the effect of the medicine may decrease. If this happens, your doctor may increase the dose so that you get adequate pain relief.

Keep enough OxyContin® tablets with you to last over weekends and holidays.

-Things you must not do

Do not drink alcohol while you are taking OxyContin® tablets.

Alcohol use could increase serious side effects of oxycodone, such as sleepiness, drowsiness, and slow or shallow breathing.

Do not take OxyContin® tablets to treat any other complaint 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, exceed the dose recommended or change the dosage without checking with your doctor.

Over time your body may become used to you taking oxycodone so if you stop taking it suddenly, your pain may worsen and you may have unwanted side effects or withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating. This is called physical dependence.

If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

- Things to be careful of

Do not drive or operate machinery until you know how OxyContin® tablets affect you.

OxyContin® tablets may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision

problems or may affect alertness.

Discuss these aspects and any impact on your driving or operating machinery with your doctor.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

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

Standing up slowly 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.

Tell your doctor if you suffer from nausea or vomiting when taking OxyContin® tablets.

If you vomit after your dose, your pain may come back, as you may not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting.

Do not be alarmed if you see remnants or the whole tablet in your stool.

The active substances have already been released in the stomach and gut, and absorbed into your body.

Tell your doctor if taking OxyContin® tablets causes constipation.

Your doctor can advise you about your diet, the proper use of laxatives and suitable exercise you can do to help you manage this.

There is potential for abuse of oxycodone and the development of addiction to oxycodone. It is important that you discuss this issue with your doctor.

Serotonin syndrome: OxyContin® may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency: Long-term use of OxyContin® may cause adrenal insufficiency, a potential life-threatening condition that may be present with a non-specific symptoms and signs such as nausea, vomiting,

decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility: Long-term use of OxyContin® may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Side effects

OxyContin® tablets can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare.

OxyContin® tablets may increase the risk of serious side effects such as a condition where you breathe more slowly or weakly than expected (respiratory depression), temporary absence or cessation of breathing, inadequate blood flow in the body, low blood pressure (hypotension) or sudden drop in blood flow through the body.

Common side effects (probably affecting more than 1 in 100 people) are listed below.

- Abdominal pain or discomfort, diarrhea, indigestion, gastritis
- Chills and fever
- Lack of appetite
- Twitching
- Abnormal dreams, anxiety, confusion, mood changes, depression, a feeling of extreme happiness, restlessness, nervousness, thought abnormalities
- Shortness of breath and hiccups
- Rash
- Low blood pressure

Uncommon side effects (probably affecting fewer than 1 in 100 people) are listed below.

- Abnormal enlargement of lymph nodes
- Hear buzzing or ringing in the ear in the absence of corresponding external sound.
- Abnormal vision
- Difficulty in swallowing, belching, wind, stomach and intestine disorder, increased appetite, inflammation inside of the mouth (stomatitis)
- Withdrawal symptoms, swelling of the hands, ankles or feet, thirst, feeling of discomfort, chest pain,

- facial swelling
- Prone to accidental injuries
- Poor blood circulation in the heart
- Dehydration
- Temporary loss of consciousness, throbbing headache, walk abnormally, partial or total loss of memory, muscle spasm, impaired or decreased tactile sensibility, low muscle tone, tingling or numbness, speech disorder, lack of consciousness, trembling or shaking, lightheadedness and unsteadiness, change in taste, sleep disorder due to breathing difficulty.
- Depression, agitation, alteration in the perception of self, mood changes, hallucination
- Painful or difficulty in passing urine, blood in the urine, excessive secretion of urine
- Impotence
- Cough increased, voice alteration
- Dry skin, inflammation of the skin

Postmarketing Experience

The following side effects have been identified during post-approval use of OxyContin® tablets

- Abuse, addiction, absence of menstrual periods, an arrest in the flow of bile, death, dental caries, abnormally increased pain sense, a condition where the bowel does not work properly (ileus), decreased muscle tone, overdose, irregular heartbeat, seizures, hives
- Life-threatening allergic reaction
- Choking, gagging, backflow, tablets stuck in the throat and difficulty swallowing the tablet
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of OxyContin®

-Storage

Keep out of the reach and sight of children. Accidental overdose by a child is dangerous and may be fatal. Do not use any tablets after the expiry date which is stated on the blister and

carton.

Do not store your tablets above 30°C.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

-What it looks like

OxyContin® tablets 10 mg are round, unscored, white-coloured, bi-convex debossed with OP on one side and 10 on the other.

OxyContin® tablets 20 mg are round, unscored, pink-coloured, bi-convex debossed with OP on one side and 20 on the other.

-Ingredients

Active ingredient

The active ingredient is oxycodone hydrochloride.

OxyContin® controlled-release tablets 10 mg contains 10mg of oxycodone hydrochloride.

OxyContin® controlled-release tablets 20 mg contains 20mg of oxycodone hydrochloride.

Inactive ingredients

The 10 mg and 20 mg tablets contain the following inactive ingredients: butylated hydroxytoluene (BHT), hypromellose, polyethylene glycol 400, polyethylene oxide, magnesium stearate, titanium dioxide.

- The 10 mg tablets also contain hydroxypropyl cellulose.
- The 20 mg tablets also contain polysorbate 80 and red iron oxide.

-MAL number:

OxyContin® controlled-release tablets 10mg - MAL14125150ACRZ

OxyContin® controlled-release tablets 20mg - MAL14125148ACRZ

Manufacturer

Knoa Pharmaceuticals LLC,
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Product Registration Holder

DKSH MALAYSIA SDN BHD
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