Oxycodone (Oral Route) Description and Brand Names

Drug information provided by: Micromedex

US Brand Name

<table>
<thead>
<tr>
<th>US Brand Name</th>
<th>Canadian Brand Name</th>
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<tr>
<td>Dazidox</td>
<td>APO-Oxycodone CR</td>
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<tr>
<td>Eth-Oxydose</td>
<td>CO oxyCODONE CR</td>
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<tr>
<td>Oxaydo</td>
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<td>OxyCONTIN</td>
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<td>OxyCONTIN CR</td>
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<td>Oxydose</td>
<td>pms-oxyCODONE</td>
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<td>Oxyfast</td>
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<td>Oxy IR</td>
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<tr>
<td>Roxicodone</td>
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<td>Roxicodone Intensol</td>
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Oxycodone is used to relieve moderate to severe pain. It belongs to the group of medicines called narcotic analgesics (pain medicines). Oxycodone acts on the central nervous system (CNS) to relieve pain.

Oxycodone extended-release tablets should not be used if you need pain medicine for just a short time, such as when recovering from surgery. Do not use this medicine to relieve mild pain, or in situations when non-narcotic medication is effective. This medicine should not be used to treat pain that you only have once in a while or "as needed".

When oxycodone is used for a long time, it may become habit-forming, causing mental or physical dependence. However, people who have continuing pain should not let the fear of dependence keep them from using narcotics to relieve their pain. Mental dependence (addiction) is not likely to occur when narcotics are used for this purpose. Physical dependence may lead to withdrawal side effects if treatment is stopped suddenly. However, severe withdrawal side effects can usually be prevented by gradually reducing the dose over a period of time before treatment is stopped completely.

This medicine is available only with your doctor’s prescription.

This product is available in the following dosage forms:
Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of Oxaydo™ and Roxicodone® in the pediatric population. Safety and efficacy have not been established.

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of Oxycontin® in children. However, safety and efficacy have not been established in children younger than 11 years of age.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of oxycodone in the elderly. However, elderly patients are more likely to have age-related lung, liver, or kidney problems, which may require caution and an adjustment in the dose for patients receiving oxycodone in order to avoid potentially serious side effects.

Pregnancy

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<th>Pregnancy Category</th>
<th>Explanation</th>
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Animal studies have shown an adverse effect and there are no adequate studies in pregnant women OR no animal studies have been conducted and there are no adequate studies in pregnant women.

Breastfeeding
Studies in women breastfeeding have demonstrated harmful infant effects. An alternative to this medication should be prescribed or you should stop breastfeeding while using this medicine.

**Drug Interactions**

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Naltrexone

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Abiraterone
- Acepromazine
- Alfentanil
- Alprazolam
- Alvimopan
- Amiodarone
- Amisulpride
- Amprenavir
- Anileridine
- Aprepitant
- Aripiprazole
- Asenapine
- Atazanavir
- Baclofen
- Benperidol
- Boceprevir
- Brofaromine
- Bromazepam
- Buprenorphine
- Buspirone
- Butorphanol
- Carisoprodol
- Carphenazine
- Ceritinib
- Chlroral Hydrate
- Chlor Diazepoxide
- Chlorpromazine
- Chlorzoxazone
- Clarithromycin
- Clobazam
- Clonazepam
- Clobazepate
- Clorgyline
- Clozapine
- Cobicistat
- Codeine
- Conivaptan
- Crizotinib
- Cyclobenzaprine
- Dabrafenib
- Darunavir
- Delavirdine
- Dexmedetomidine
- Dezocine
- Diacetyl morphine
- Diazepam
- Dichloralphenazone
- Difenoxin
- Dihydrocodeine
- Diphenhydramine
- Diphenoxylate
- Donepezil
- Doxylamine
- Droperidol
- Enflurane
- Erythromycin
- Escitalopram
- Estazolam
- Eszopiclone
- Ethchlorvynol
- Ethopropazine
- Ethylmorphine
- Etomidate
- Fentanyl
- Flibanserin
- Flunitrazepam
- Fluphenazine
- Flurazepam
- Fluspirilene
- Fluvoxamine
- Fosaprepitant
- Fospropofol
- Furazolidone
- Halazepam
- Haloperidol
- Halothane
- Hexobarbital
- Hydrocodone
- Hydromorphone
- Hydroxyzine
- Idelalisib
- Imatinib
- Indinavir
- Iproniazid
- Isocarboxazid
- Isoflurane
- Ketamine
- Ketazolam
- Ketobemidone
- Ketoconazole
- Lazabemide
- Levorphanol
- Linezolid
- Lomitapide
- Loprazolam
- Lorazepam
- Lormetazepam
- Meclizine
- Medazepam
- Melperone
- Meperidine
- Meptazinol
- Mesoridazine
- Metaxalone
- Methadone
- Methdilazine
- Methocarbamol
- Methohexital
- Methotrimeprazine
- Methylene Blue
- Methylnaltrexone
- Midazolam
- Mifepristone
- Moclobemide
- Molindone
- Moricizine
- Morphine
- Morphine Sulfate Liposome
- Nalbuphine
- Nalmefene
- Nalorphine
- Naloxone
- Nefazodone
- Nelfinavir
- Nialamide
- Nicomorphine
- Nilotinib
- Nitrazepam
- Nitrous Oxide
- Olanzapine
- Opium
- Orphenadrine
- Oxazepam
- Oxycodone
- Oxymorphone
- Papaveretum
- Paregoric
- Pargyline
- Pentazocine
- Perazine
- Periciazine
- Perphenazine
- Phenelzine
- Pimozide
- Piperacetazine
- Piperaquine
- Pipotiazine
- Piritramide
- Posaconazole
- Prazepam
- Procarbazine
- Prochlorperazine
- Promazine
- Promethazine
- Propofol
- Propoxyphene
- Quazepam
- Quetiapine
- Ramelteon
- Rasagiline
- Regorafenib
- Remifentanil
- Remoxipride
- Ritonavir
- Samidorphan
- Saquinavir
- Selegiline
- Sertindole
- Sertraline
- Sodium Oxybate
- Sufentanil
- Sulpiride
- Suvorexant
- Tapentadol
- Telaprevir
- Telithromycin
- Temazepam
- Thiopropazate
- Thioridazine
- Ticagrelor
- Tilidine
- Tizanidine
- Tolonium Chloride
- Toloxatone
- Topiramate
- Tramadol
- Tranylcypromine
- Triazolam
- Trifluoperazine
- Trifluperidol
- Triflupromazine
- Trimeprazine
- Zaleplon
- Zolpidem
- Zopiclone
• Zotepine

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

• Miconazole
• Rifampin
• St John's Wort
• Voriconazole

Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following is usually not recommended, but may be unavoidable in some cases. If used together, your doctor may change the dose or how often you use this medicine, or give you special instructions about the use of food, alcohol, or tobacco.

• Ethanol

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

• Addison's disease (adrenal gland problem) or
• Alcohol abuse, or history of or
• Brain tumor, history of or
• Breathing problems (eg, hypoxia) or
• Cancer of the esophagus or colon or
• Central nervous system (CNS) depression or
• Chronic obstructive pulmonary disease (COPD) or
• Cor pulmonale (serious heart condition) or
• Drug dependence, especially with narcotics, or history of or
• Enlarged prostate (BPH, prostatic hypertrophy) or
• Gallbladder disease or gallstones or
• Head injuries, history of or
• Hypothyroidism (an underactive thyroid) or
• Hypovolemia (low blood volume) or
• Kyphoscoliosis (curvature of the spine with breathing problems) or
• Problems with passing urine or
• Psychosis (a mental disease) or
• Trouble swallowing or
• Weakened physical condition—Use with caution. May increase risk for more serious side effects.
• Asthma, severe or
• Hypercarbia (high carbon dioxide in the blood) or
• Paralytic ileus (intestine stops working and may be blocked) or
• Respiratory depression (very slow breathing) or
• Stomach or bowel blockage—Should not be used in patients with these conditions.
• Hypotension (low blood pressure) or
• Pancreatitis (inflammation or swelling of the pancreas) or
• Seizures, history of—Use with caution. May make these conditions worse.
• Kidney disease, severe or
• Liver disease—Use with caution. The effects may be increased because of slower removal of the medicine from the body.

Proper Use

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. This is especially important for elderly patients, who may be more sensitive to the effects of pain medicines. If too much of this medicine is taken for a long time, it may become habit-forming (causing mental or physical dependence).

This medicine comes with a Medication Guide and a patient information leaflet. Read and follow these instructions carefully. Ask your doctor if you have any questions.

Oxycodone extended-release tablets should only be used by patients who have already been taking narcotic pain medicines, also called opioids. These patients are called opioid-tolerant. If you are uncertain whether or not you are opioid-tolerant, check with your doctor before using this medicine.

Measure the oral liquid concentrate with the calibrated dropper that comes with the package. Your doctor may have you mix the concentrate with a small amount of liquid or food. Carefully follow the instructions and take the medicine mixture right away.

Measure the oral liquid with a marked measuring spoon, oral syringe, or medicine cup. The average household teaspoon may not hold the right amount of liquid.
Swallow the Oxaydo™ or OxyContin® tablet whole with water. Do not break, crush, cut, chew, or dissolve it. Do not pre-soak, lick, or wet the tablet before placing it in the mouth. Take one tablet at a time. Also, do not give this medicine through nasogastric or feeding tubes.

Oxycodone extended-release tablets work differently from the regular oxycodone oral solution or tablets, even at the same dose. Do not switch from one brand or form to the other unless your doctor tells you to.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor’s orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (extended-release tablets):
  - For moderate to severe pain:
    - Patients switching from regular oxycodone forms:
      - Adults—The tablet is given every 12 hours. The total amount of milligrams (mg) per day is the same as the total amount of regular oxycodone that is taken per day. The total amount per day will be divided and given as 2 doses during the day. Your doctor may adjust your dose if needed.
      - Children 11 years of age and older—Dose must be determined by your doctor. The patient must already be receiving and tolerating opioids for at least 5 consecutive days with a minimum of 20 mg per day of oxycodone or its equivalent for at least 2 days before taking OxyContin®.
      - Children younger than 11 years of age—Use and dose must be determined by your doctor.
    - Patients switching from other narcotic medicines:
      - Adults—The tablet is given every 12 hours. The total amount of milligrams (mg) per day will be determined by your doctor and depends on which narcotic you were using. The total amount per day will be divided and given as 2 doses during the day. Your doctor may adjust your dose if needed.
      - Children 11 years of age and older—Dose must be determined by your doctor. The patient must already be receiving and tolerating opioids for at least 5 consecutive days with a minimum of 20 mg per day of oxycodone or its equivalent for at least 2 days before taking OxyContin®.
      - Children younger than 11 years of age—Use and dose must be determined by your doctor.
    - Patients who are not taking narcotic medicines:
- Adults—At first, 10 milligrams (mg) every 12 hours. Your doctor may adjust your dose if needed.
- Children—Use and dose must be determined by your doctor.

- For oral dosage form (immediate-release tablets):
  - For moderate to severe pain:
    - Patients who are not taking narcotic medicines:
      - Adults—At first, 5 to 15 milligrams (mg) every 4 to 6 hours as needed. Your doctor may adjust your dose if needed.
      - Children—Use and dose must be determined by your doctor.
    - Patients switching from fixed-ratio oral narcotic/non-narcotic combinations:
      - Adults—Your doctor will determine whether or not to continue the non-narcotic pain medicine. Also, the total amount of milligrams (mg) per day will be determined by your doctor and depends on which narcotic you were using. Your doctor may adjust your dose if needed.
      - Children—Use and dose must be determined by your doctor.
    - Patients switching from other narcotic medicines:
      - Adults—The total amount of milligrams (mg) per day will be determined by your doctor and depends on which narcotic you were using. Your doctor may adjust your dose if needed.
      - Children—Use and dose must be determined by your doctor.

- For oral dosage forms (liquid concentrate, solution, or tablets):
  - For moderate to severe pain:
    - Adults—10 to 30 milligrams (mg) every 4 hours as needed. Your doctor may adjust your dose if needed.
    - Children—Use and dose must be determined by your doctor.

**Missed Dose**

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

**Storage**

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.
Oxycodone can cause serious unwanted effects if taken by adults who are not used to strong narcotic pain medicines, children, or pets. Make sure you store the medicine in a safe and secure place to prevent others from getting it.

Flush the unused extended-release tablets and immediate-release tablets down the toilet.

Precautions

It is very important that your doctor check your progress while you are taking this medicine. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it.

This medicine may cause a serious type of allergic reaction called anaphylaxis. Anaphylaxis can be life-threatening and requires immediate medical attention. Call your doctor right away if you have a rash, itching, hoarseness, trouble breathing, trouble swallowing, or any swelling of your hands, face, or mouth while you are using this medicine.

Do not use more of this medicine or take it more often than your doctor tells you to. This can be life-threatening. Symptoms of an overdose include extreme dizziness or weakness, slow heartbeat or breathing, seizures, trouble breathing, and cold, clammy skin. Call your doctor right away if you notice these symptoms.

This medicine will add to the effects of alcohol and other CNS depressants (medicines that can make you drowsy or less alert). Some examples of CNS depressants are antihistamines or medicine for allergies or colds, sedatives, tranquilizers, or sleeping medicine, other prescription pain medicine or narcotics, medicine for seizures or barbiturates, muscle relaxants, or anesthetics, including some dental anesthetics. Check with your doctor before taking any of these medicines while you are using this medicine.

This medicine may be habit-forming. If you feel that the medicine is not working as well, do not use more than your prescribed dose. Call your doctor for instructions.

Dizziness, lightheadedness, or fainting may occur when you get up suddenly from a lying or sitting position. Getting up slowly may help lessen this problem. Also, lying down for a while may relieve the dizziness or lightheadedness.

This medicine may make you dizzy, drowsy, or lightheaded. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or not alert.

Using narcotics for a long time can cause severe constipation. To prevent this, your doctor may direct you to take laxatives, drink a lot of fluids, or increase the amount of fiber in your diet. Be sure to follow the directions carefully, because continuing constipation can lead to more serious problems.

If you have been using this medicine regularly for several weeks or longer, do not change your dose or suddenly stop using it without checking with your doctor. Your doctor may want you to gradually reduce the amount you are using before stopping it completely. This may help prevent
worsening of your condition and reduce the possibility of withdrawal symptoms, such as abdominal or stomach cramps, anxiety, fever, nausea, runny nose, sweating, tremors, or trouble sleeping.

Using this medicine while you are pregnant may cause serious unwanted effects in your newborn baby. Tell your doctor right away if you think you are pregnant or if you plan to become pregnant while using this medicine.

Make sure any doctor or dentist who treats you knows that you are using this medicine. This medicine may affect the results of certain medical tests.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

**Side Effects**

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

**Less common**

- Chills
- cold sweats
- confusion
- difficult or labored breathing
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- fever
- tightness in the chest
- twitching

**Rare**

- Abdominal or stomach pain
- bloating or swelling of the face, arms, hands, lower legs, or feet
- blood in the urine
- burning while urinating burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- chest pain
- convulsions
- cough
- decrease in the frequency of urination
- decrease in urine volume
- decreased urine output
- difficult or painful urination
- difficulty in passing urine (dribbling)
- difficulty with swallowing
- dizziness
- dry mouth
- fainting
- fast, irregular, pounding, or racing heartbeat or pulse
- feeling of warmth or heat
- flushing or redness of the skin, especially on the face and neck
- frequent urination
- headache
- hives, itching, or skin rash
- increase in heart rate
- increased thirst
- increased volume of pale, dilute urine
- lightheadedness
- muscle pain or cramps
- nausea or vomiting
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- rapid breathing
- rapid weight gain
- severe constipation
- severe vomiting
- shakiness in the legs, arms, hands, or feet
- sunken eyes
- sweating
- swelling or puffiness of the face
- swollen, painful, or tender lymph glands in the neck, armpit, or groin
- thirst
- tingling of the hands or feet
- trembling or shaking of the hands or feet
- unusual tiredness or weakness
- unusual weight gain or loss
• wrinkled skin

**Incidence not known**

• Blurred vision
• choking
• clay-colored stools
• cold, clammy skin
• dark urine
• diarrhea
• fast, weak pulse
• gagging
• irregular, fast, slow, or shallow breathing
• loss of appetite
• pale or blue lips, fingernails, or skin
• unconsciousness
• unpleasant breath odor
• very slow heartbeat
• yellow eyes or skin

Get emergency help immediately if any of the following symptoms of overdose occur:

**Symptoms of overdose**

• Change in consciousness
• chest pain or discomfort
• constricted, pinpoint, or small pupils (black part of the eye)
• decreased awareness or responsiveness
• extreme drowsiness
• loss of consciousness
• no muscle tone or movement
• severe sleepiness
• slow or irregular heartbeat

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

**More common**
• Difficulty having a bowel movement (stool)
• drowsiness
• lack or loss of strength
• relaxed and calm feeling
• sleepiness or unusual drowsiness

Less common
• Abnormal dreams
• acid or sour stomach
• anxiety
• belching
• burning feeling in the chest or stomach
• false or unusual sense of well-being
• heartburn
• hiccups
• indigestion
• stomach discomfort, upset, or pain
• tenderness in the stomach area
• trouble sleeping
• weight loss

Rare
• Absent, missed, or irregular menstrual periods
• bad, unusual or unpleasant (after) taste
• bloated or full feeling
• body aches or pain
• change in taste
• change in walking and balance
• changes in vision
• clumsiness or unsteadiness
• congestion
• continuing ringing or buzzing or other unexplained noise in the ears
• cracks in the skin
• crying
• decreased interest in sexual intercourse
• dental caries or tooth decay
- depersonalization
- depression
- difficulty with speaking
- dry skin
- dryness or soreness of the throat
- dysphoria
- excess air or gas in the stomach or intestines
- excessive muscle tone
- feeling of constant movement of self or surroundings
- feeling of unreality
- general feeling of discomfort or illness
- headache, severe and throbbing
- hearing loss
- hoarseness
- hyperventilation
- inability to have or keep an erection
- increase in body movements
- increased appetite
- increased cough
- irritability
- loss in sexual ability, desire, drive, or performance
- loss of heat from the body
- loss of memory
- loss of strength or energy
- mental depression
- muscle pain or weakness
- muscle stiffness
- muscle tension or tightness
- neck pain
- paranoia
- passing of gas
- problems with memory
- quick to react or overreact emotionally
- rapidly changing moods
- red, swollen skin
- restlessness
- runny nose
- scaly skin
- sensation of spinning
- sense of detachment from self or body
- severe sleepiness
- stomach pain, fullness, or discomfort
- stopping of menstrual bleeding
- swelling or inflammation of the mouth
- tender, swollen glands in the neck
- unusual weak feeling
- voice changes

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.
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