

Table with 2 columns: Category and Description. Categories include Monoamine Oxidase Inhibitors (MAOIs), Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics, Muscle Relaxants, Diuretics, and Anticholinergic Drugs.

8. USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary

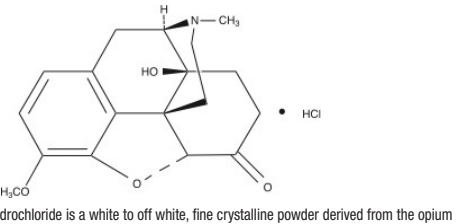
Prolonged use of opioid analgesics during pregnancy may cause neonatal opioid withdrawal syndrome [see Warnings and Precautions (5.4)]. Available data with Oxycodone Hydrochloride Oral Solution are insufficient to inform a drug-associated risk for major birth defects and miscarriage.

Animal reproduction studies with oral administrations of oxycodone hydrochloride in rats and rabbits during the period of organogenesis at doses 2.6 and 8.1 times, respectively, the human dose of 60 mg/day did not reveal evidence of teratogenicity or embryo-fetal toxicity.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Animal Data
In embryo-fetal development studies in rats and rabbits, pregnant animals received oral doses of oxycodone hydrochloride administered during the period of organogenesis up to 16 mg/kg/day and up to 25 mg/kg/day, respectively. These studies revealed no evidence of teratogenicity or embryo-fetal toxicity due to oxycodone.

11 DESCRIPTION
Oxycodone Hydrochloride Oral Solution, USP is an agonist, available as a clear colorless solution 5 mg/5 mL (1 mg/mL) and a light orange clear solution 100 mg/5 mL (20 mg/mL) for oral administration. The chemical name is (5R,9R,13S,14S)-4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride.



12.1 CLINICAL PHARMACOLOGY
12.1.1 Mechanism of Action
Oxycodone is a full opioid agonist and is relatively selective for the mu-opioid receptor, although it can bind to other opioid receptors at higher doses.

9.2 Abuse
Oxycodone Hydrochloride Oral Solution contains oxycodone, a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxymorphone, and tapentadol.

Prescription drug abuse is the intentional non-therapeutic use of a prescription drug, even once, for its rewarding psychological or physiological effects.

Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and includes: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal.

"Drug-seeking" behavior is very common in persons with substance use disorders. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing, or referral, repeated "loss" of prescriptions, tampering with prescriptions, and reluctance to provide prior medical records or contact information for other treating health care providers.

Abuse and addiction are separate and distinct from physical dependence and tolerance. Health care providers should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts.

Oxycodone Hydrochloride Oral Solution, like other opioids, can be diverted for non-medical use into illicit channels of distribution. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests, as required by state and federal law, is strongly advised.

Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

Risks Specific to Abuse of Oxycodone Hydrochloride Oral Solution
Oxycodone Hydrochloride Oral Solution is for oral use only. Abuse of oxycodone poses a risk of overdose and death. The risk is increased with concurrent abuse of alcohol and other central nervous system depressants.

9.3 Dependence
Both tolerance and physical dependence can develop during chronic opioid therapy. Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors).

Physical dependence results in withdrawal symptoms after abrupt discontinuation or a significant dosage reduction of a drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity (e.g., naloxone, nalmefene), mixed agonist/antagonist analgesics (e.g., pentazocine, butorphanol, nalbuphine), or partial agonists (e.g., buprenorphine).

Oxycodone Hydrochloride Oral Solution should not be abruptly discontinued in a physically-dependent patient [see Dosage and Administration (2.4)].

Oxycodone Hydrochloride Oral Solution is abruptly discontinued in a physically-dependent patient, a withdrawal syndrome may occur. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis.

Other signs and symptoms also may develop, including irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate.

Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal signs [see Use in Specific Populations (8.1)].

10 OVERDOSAGE
Clinical Presentation
Acute overdose with Oxycodone Hydrochloride Oral Solution can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring, and death.

In case of overdose, priorities are the reestablishment of a patent and protected airway and institution of assisted or controlled ventilation, if needed. Employ other supportive measures (including oxygen and vasopressors) in the management of circulatory shock and pulmonary edema as indicated.

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12.2 Pharmacodynamics
Effects of the Central Nervous System (CNS)
Oxycodone produces respiratory depression by direct action on brain stem respiratory centers. The respiratory depression involves a reduction in the responsiveness of the brain stem respiratory centers to both increases in carbon dioxide tension and electrical stimulation.

12.3 Pharmacokinetics
The activity of oxycodone hydrochloride is primarily due to the parent drug oxycodone. About 60 to 87% of an oral dose reaches the systemic circulation in comparison to a parenteral dose.

12.4 Distribution
Following intravenous administration, the volume of distribution (Vss) for oxycodone was 2.6 L/kg. Plasma protein binding of oxycodone at 37°C and a pH of 7.4 was about 45%.

12.5 Elimination
Metabolism
Oxycodone hydrochloride is extensively metabolized by multiple metabolic pathways to noroxycodone, oxymorphone, and noroxymorphone, which are subsequently glucuronidated.

12.6 Excretion
Oxycodone and its metabolites are excreted primarily via the kidney. The amounts measured in the urine have been reported as follows: free oxycodone up to 19%; conjugated oxycodone up to 50%; free oxymorphone 0%; conjugated oxymorphone < 14%.

12.7 Specific Populations
Age: Geriatric Population:
Information obtained from oxycodone tablets indicate that the plasma concentrations of oxycodone did not appear to be increased in patients over the age of 65.

12.8 Pregnancy
Because oxycodone is extensively metabolized in the liver, its clearance may decrease in hepatic-impaired patients. A dose adjustment is recommended in these patients [see Use in Specific Populations (8.6)].

12.9 Renal Impairment
Information from oxycodone tablets indicate that patients with renal impairment had higher plasma concentrations of oxycodone than subjects with normal renal function.

12.10 Abuse and Dependence
Oxycodone Hydrochloride Oral Solution contains oxycodone, a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxymorphone, and tapentadol.

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JOB SPECIFICATION FORM

Job #:

Customer Name:

Customer Rep:

Date Submitted:

JOB INFO

Job Name:

Type: New Design ()

Reprint ()

File Name:

JOB TYPE: () **Insert**

() **Med Guide**

() **Patient Guide**

Rev:

Proof #:

Grain direction:

Manufacture by:

Manufacture for:

Fold Type:

Flat Size:

Final Folded size:

Finishing For Padding:

Customer Item #:

Barcode Reader:

Paper Stock:

Ink:

Notes

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