

**OXYCODONE HYDROCHLORIDE ORAL SOLUTION USP, 5 mg per 5 mL
OXYCODONE HYDROCHLORIDE ORAL CONCENTRATE SOLUTION, 20 mg per mL
OXYCODONE HYDROCHLORIDE ORAL CONCENTRATE SOLUTION
(Raspberry Flavored), 20 mg per mL
Rx only**



DESCRIPTION

Each 5 mL of the Oral Solution contains: Oxycodone Hydrochloride 5 mg

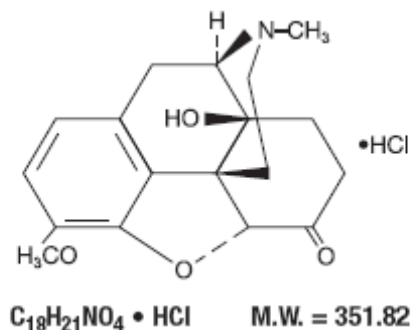
Each mL of the Oral Concentrate Solution (unflavored and flavored) contains: Oxycodone Hydrochloride 20 mg

Inactive Ingredients

The Oral Solution contains artificial raspberry flavor, citric acid, FD&C Red No. 40, glycerin, hydrochloric acid, Poloxamer 188, purified water, sodium benzoate and sorbitol.

The Oral Concentrate Solution, unflavored and flavored, contains citric acid, D&C Yellow No. 10, hydrochloric acid, purified water, sodium benzoate and sodium saccharin. The flavored solution also contains artificial raspberry flavor.

Oxycodone hydrochloride is 4,5 α -epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride, a white odorless crystalline powder which is derived from the opium alkaloid, thebaine, and may be represented by the following structural formula:



ACTIONS

The analgesic ingredient, oxycodone, is a semi-synthetic narcotic with multiple actions qualitatively similar to those of morphine; the most prominent of these involve the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value of oxycodone are analgesia and sedation.

Oxycodone is similar to codeine and methadone in that it retains at least one half of its analgesic activity when administered orally.

INDICATIONS

For the relief of moderate to moderately severe pain.

CONTRAINDICATIONS

Hypersensitivity to oxycodone.

WARNINGS

Drug Dependence – Oxycodone can produce drug dependence of the morphine type, and therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of this drug, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications. Like other narcotic-containing medications, this drug is subject to the Federal Controlled Substances Act.

Usage in Ambulatory Patients – Oxycodone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using this drug should be cautioned accordingly.

Interaction with Other Central Nervous System Depressants – Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative hypnotics or other CNS depressants (including alcohol) concomitantly with oxycodone hydrochloride may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.

Usage in Pregnancy – Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, this drug should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards.

Usage in Children – This drug should not be administered to children.

PRECAUTIONS

Head Injury and Increased Intracranial Pressure – The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions – The administration of this drug or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special Risk Patients – This drug should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease and prostatic hypertrophy or urethral stricture.

ADVERSE REACTIONS

The most frequently observed adverse reactions include light-headedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include euphoria, dysphoria, constipation, skin rash and pruritus.

DOSAGE AND ADMINISTRATION

The usual adult oral dose is 10 to 30 mg every 4 hours as needed for pain or as directed by physician. The dose must be individually adjusted according to severity of pain, patient response and patient size. More severe pain may require 30 mg or more every 4 hours. If the pain increases in severity, analgesia is not adequate or tolerance occurs, a gradual increase in dosage may be required.

For control of severe, chronic pain in patients with certain terminal diseases, this drug should be administered on a regularly scheduled basis, every 4 hours, at the lowest dosage level that will achieve adequate analgesia.

DRUG INTERACTIONS

The CNS depressant effects of oxycodone hydrochloride may be additive with that of other CNS depressants (*see* **WARNINGS**).

MANAGEMENT OF OVERDOSAGE

Signs and Symptoms – Serious overdose of oxycodone hydrochloride is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.

Treatment – Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including oxycodone. Therefore, an appropriate dose of naloxone (usual initial adult dose: 0.4 mg) should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression.

Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

HOW SUPPLIED

Oral Solution USP

The Oral Solution USP 5 mg per 5 mL, is available as a red, raspberry flavored liquid.

Bottles of 500 mL NDC 0406-8555-50

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

PROTECT FROM LIGHT.

Dispense in a tight, light-resistant container with a child-resistant closure.

Oral Concentrate Solutions

Unflavored

The Oral Concentrate Solution, 20 mg per mL, is available as a yellow, unflavored liquid.

Supplied with calibrated syringe [graduations of 0.25 mL (5 mg), 0.5 mL (10 mg), 0.75 mL (15 mg), and 1.0 mL (20 mg) on the syringe].

Bottles of 30 mL NDC 0406-8558-30

Flavored

The Oral Concentrate Solution (Raspberry Flavored), 20 mg per mL, is available as a clear, yellow liquid with raspberry odor.

Supplied with calibrated syringe [graduations of 0.25 mL (5 mg), 0.5 mL (10 mg), 0.75 mL (15 mg), and 1.0 mL (20 mg) on the syringe].

Bottles of 30 mL NDC 0406-8668-30

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

PROTECT FROM LIGHT.

Dispense in a tight, light-resistant container with a child-resistant closure.

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Rev 010609