Epic Oxycodone Hydrochloride Tablets

Size: 10.562 x 10.062
Fold: 1/1-8 x 1/1-8
Type: 5.5 pt.
Page: 1

Clinical Pharmacology

Pharmacokinetics: Oxycodone is a weak analgesic that is rapidly absorbed after oral administration. It is extensively metabolized by the liver and excreted in the urine. Oxycodone is a prodrug and is converted to its active metabolites, which are primarily oxycodone glucuronide and oxycodone sulfate. These metabolites are excreted in the urine. The plasma half-life of oxycodone is approximately 2-4 hours.

Absorption: Oxycodone is well absorbed after oral administration, with peak plasma concentrations achieved within 1-2 hours. The absolute bioavailability of oxycodone hydrochloride tablets is 30-40%.

Distribution: The volume of distribution of oxycodone is approximately 1.5 L/kg and is not different from that of the plasma.

Metabolism: Oxycodone is metabolized in the liver by the cytochrome P450 enzyme system, primarily by CYP3A4, and the metabolites are excreted in the urine.

Excretion: Oxycodone is excreted primarily in the urine as conjugates of the inactive metabolites. The elimination half-life of oxycodone is approximately 2-4 hours.

Dosage and Administration:

Adults: The usual starting dose of oxycodone hydrochloride tablets is 5 mg every 4-6 hours, as needed for pain. The dose may be increased or decreased based on the individual patient's response and tolerance. The maximum daily dose is 240 mg for adults.

Pediatric Patients: The safety and effectiveness of oxycodone hydrochloride tablets in pediatric patients have not been established. The usual starting dose is 0.1-0.2 mg/kg every 4-6 hours, as needed for pain. The dose may be increased or decreased based on the individual patient's response and tolerance.

Geriatric Patients: Oxycodone hydrochloride tablets should be used with caution in elderly patients, as they may be more sensitive to the effects of oxycodone due to age-related changes in drug disposition. The starting dose may be lower, and dose increments should be smaller.

Drug-Drug Interactions:

- Oxycodone hydrochloride tablets may increase the risk of adverse effects if used with other centrally acting drugs that depress the central nervous system, such as sedative/hypnotics, alcohol, or other drugs that may cause respiratory depression.
- Oxycodone hydrochloride tablets should be used with caution with drugs that are metabolized by CYP3A4, such as calcium channel blockers, and with CYP3A4 inhibitors, such as macrolide antibiotics. Use of these concomitant medications may increase the risk of adverse effects.
- Caution is recommended when using oxycodone hydrochloride tablets with other drugs that are metabolized by CYP2D6, as this may increase the risk of adverse effects or toxicity.

Overdose:

If a patient has ingested an overdose of oxycodone hydrochloride tablets, immediate medical attention should be sought. Treatment should include supportive care, such as respiratory support and intravenous fluids, as indicated.

Potential Emergency Department Treatment:

- NG gastric lavage of the stomach to remove any unabsorbed drug.
- Oxygenation and ventilation support if respiratory depression occurs.
- Intravenous fluids, if dehydration or hypovolemia is present.
- Adjunctive therapies, such as naloxone, if the patient is a known opioid-dependent individual.

Respiratory Depression:

- Oxygen therapy: Oxygen should be administered as necessary.
- Naloxone: This opioid antagonist can reverse respiratory depression caused by overdosage or administration into a patient who is not opioid dependent.
- Noninvasive positive pressure ventilation: This method can be effective in treatment of severe respiratory depression.
- Intubation and mechanical ventilation: May be required for severe cases where noninvasive methods are ineffective.

Data from Practical Emergency Department Treatment: The administration of naloxone in cases of severe respiratory depression has resulted in significant improvement in respiratory function, leading to a decrease in mortality. In addition, naloxone administration has been associated with a decrease in the rate of naloxone administration in opioid-dependent patients.

Other Important Information:

- Oxycodone hydrochloride tablets should be kept out of reach of children. In case of ingestion by children, contact a Poison Control Center or seek immediate medical attention.
- Oxycodone hydrochloride tablets are available in strengths of 5 mg and 10 mg.

Precautions:

- Oxycodone hydrochloride tablets should be used with caution in patients with a history of drug abuse, alcoholism, or other conditions that may precipitate respiratory depression.
- Oxycodone hydrochloride tablets should be used with caution in patients with hepatic or renal impairment.
- Oxycodone hydrochloride tablets should be used with caution in patients with a history of seizures.
- Oxycodone hydrochloride tablets should be used with caution in patients with a history of chronic obstructive pulmonary disease.
- Oxycodone hydrochloride tablets should be used with caution in patients with a history of asthma.
- Oxycodone hydrochloride tablets should be used with caution in patients with a history of allergic reactions to other opioids.

References:

- American Society of Health-System Pharmacists: Opioid Analgesics. 2021. Available at: https://www.ashp.org/Practitioner/Products-Publications/Books/Opioid-Analgesics
- United States Food and Drug Administration: Opioid Analgesics. 2021. Available at: https://www.fda.gov/drugs/categories-opioids}

Confidential
due to the risk of precipitating withdrawal symptoms. Their physician can provide a dose schedule to help the patient gradually reduce the dose to accommodate a gradual discontinuation of the medication.

Drug Interactions: Oxycodone is metabolized in part by the cytochrome P450 3A4 (CYP3A4) enzyme. While this pathway is only a small fraction of the overall metabolism of oxycodone, a variety of drugs, including certain cardiovascular drugs and antidepressants, may block this pathway, leading to increased plasma levels of oxycodone and possible toxicity. Therefore, it is important to be cautious in prescribing oxycodone to patients who are also taking medications that inhibit this enzyme.

CNS Depressants: Patients receiving narcotic analgesics, general anesthetics, phenothiazines, or other CNS depressants (including alcohol) concurrently with oxycodone hydrochloride tablets may exhibit an additive CNS depression. Interactions resulting in respiratory depression, hypotension, profound sedation, or coma may result if these drugs are taken in combination with the usual dosage of oxycodone hydrochloride tablets. When such combined therapy is contemplated, the dose of one or both agents should be reduced.

Mixed Agonists/Agonist Analgesic: Agonist/agonist analgesics (i.e., pentazocine, levorphanol, and butorphanol) should be administered with caution to patients who have received or are receiving a course of therapy with a pure opioid agonist analgesic such as oxycodone hydrochloride tablets. In this situation, mixed agonist/agonist analgesics may analogize the additive effect of oxycodone hydrochloride tablets and/or precipitate withdrawal symptoms in these patients.

Geriatric Use: Oxycodone hydrochloride tablets should not be used in patients with hepatic impairment, severe renal impairment, or patients who have received or are receiving a course of therapy with a pure opioid agonist analgesic such as oxycodone hydrochloride tablets.

Drug Interactions: Coadministration of oxycodone hydrochloride tablets with other CNS depressants may result in additive CNS depression. Therefore, caution should be exercised when oxycodone hydrochloride tablets are administered with other CNS depressants, including alcohol, general anesthetics, sedative/hypnotics, and other opioid analgesics.

Neuromuscular Blocking Agents: The neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of muscle blockade. The degree of blockade is related to the dose and duration of administration of the muscle relaxant and the individual variation in sensitivity. The degree of blockade may be potentiated by concomitant administration of certain opioids (e.g., fentanyl, alfentanil).

Drug Interactions: Oxycodone hydrochloride tablets are intended for the management of moderate to severe pain in patients who require treatment with an oral opioid analgesic. The dose should be individually adjusted according to severity of pain, patient, and pain site. If the dose increases in severity, if analgesia is not adequate, or if tolerance occurs, a gradual increase in dosage may be required. Patients who have not been receiving opioid analgesics should be started on oxycodone hydrochloride tablets in a dosage range of 5 to 15 mg every 4 to 6 hours as needed for pain. The dose should be titrated based on the individual patient’s response to their initial dose of oxycodone hydrochloride tablets. Patients with chronic pain should be started on oxycodone hydrochloride tablets at a lower dose and titrated upward to the lowest effective dose to prevent the reoccurrence of pain rather than treating the pain after it has occurred. This dose can then be adjusted to an acceptable level of analgesia taking into account side effects experienced by the patient.

Control of Severe Chronic Pain: Oxycodone hydrochloride tablets should be administered on a regular (around-the-clock) basis, every 4 to 6 hours, at the lowest dosage level that will achieve adequate analgesia.

Conversion From Fixed-Ratio Opioid/Nonsteroidal, Oxycodone/Acetaminophen, or Oxycodone/Nonsteroidal Combination Drugs: When converting patients from fixed-ratio oxycodone/nonsteroidal opioid regimens a decision should be made whether or not to continue the non-opioid component. If a decision is made to discontinue the use of non-opioid analgesics, it may be necessary to titrate the dose of oxycodone hydrochloride tablets in response to the level of analgesic and adverse effects afforded by the dosing regimen. If the non-opioid regimen is continued as a co-analgesic, oxycodone hydrochloride tablets should be based upon the most recent dose of oxicodone as a baseline for further titration of oxycodone. Incremental increases should be made and gradually tapered according to side effects to as acceptable level of analgesia.

Patients Currently on Opioid Therapy: If a patient has been receiving opioid-containing medications prior to taking oxycodone hydrochloride tablets, the potential for the prior opioid to result in opioid antagonize the patient should be factored into the selection of the daily dosage of oxycodone hydrochloride tablets.

In converting patients from other opioids to oxycodone hydrochloride tablets, close observation and adjustment of dosage based upon the patient’s response to oxycodone hydrochloride tablets may be necessary because oxycodone hydrochloride tablets are not recommended for use in women during or immediately prior to labor and delivery.

Pregnancy and Nursing: If a patient has been receiving opioid-containing medications prior to starting oxycodone hydrochloride tablets, the potential for the prior opioid to result in opioid antagonize the patient should be factored into the selection of the daily dosage of oxycodone hydrochloride tablets.

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