Roxicodone (oxycodone hydrochloride) - Drug Summary

Mallinckrodt, Inc.

Related Drug Information

Oxycodone Tablets (oxycodone hydrochloride)

COMMON BRAND NAMES

Roxicodone, Oxycodone Tablets

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Moderate to Severe Pain

Opioid-Naive:
Initial: 5-15mg q4-6h prn
Titrate: Adjust dose based upon response

For chronic pain, give on an around-the-clock basis
For severe chronic pain, give q4-6h at the lowest effective dose

Conversions

From Fixed-Ratio Opioid/Acetaminophen, Opioid/Aspirin, or Opioid/Nonsteroidal Combination Drugs:
Decision should be made whether or not to continue the nonopioid analgesic

Discontinuing Nonopioid Analgesic:
May be necessary to titrate to the minimum effective dose

Continuing Nonopioid Regimen as a Separate Single Entity Agent:
Starting dose of oxycodone should be based upon the most recent dose of opioid as a baseline for further titration of oxycodone
Incremental increases should be gauged according to side effects to an acceptable level of analgesia

From Other Opioids:
Factor the potency of the prior opioid relative to oxycodone to select the total daily dose
Closely observe and adjust dose based on response

DOSING CONSIDERATIONS

Renal Impairment
Initial: Dose conservatively
Titrate: Adjust according to clinical situation

Hepatic Impairment
Initial: Dose conservatively
Titrate: Adjust according to clinical situation

Discontinuation
D/C gradually; decrease by 25-50% per day
Raise dose to previous level and titrate down more slowly if withdrawal symptoms occur

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab: 10mg*, 20mg*; (Roxicodone) 5mg*, 15mg*, 30mg* *scored

CONTRAINDICATIONS

Significant respiratory depression (in unmonitored settings or the absence of resuscitative equipment), paralytic ileus, acute or severe bronchial asthma or hypercarbia.

WARNINGS/PRECAUTIONS

Respiratory depression may occur; extreme caution with significant chronic obstructive pulmonary disease or cor pulmonale, substantially decreased respiratory reserve, hypoxia, hypercapnia, preexisting respiratory depression, and in the elderly/debilitated. May cause severe hypotension; caution with circulatory shock. May produce orthostatic hypotension in ambulatory patients. Respiratory depressant effects and capacity to elevate CSF pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or preexisting increased intracranial pressure. May obscure the clinical course of patients with head injuries. Caution with acute alcoholism, adrenocortical insufficiency (eg, Addison's disease), convulsive disorders, CNS depression or coma, delirium tremens, kyphoscoliosis associated with respiratory depression, myxedema or hypothyroidism, prostatic hypertrophy or urethral stricture, severe hepatic/renal/pulmonary impairment, and toxic psychosis. May obscure diagnosis or clinical course in patients with acute abdominal conditions. May aggravate convulsions with convulsive disorders and may induce or aggravate seizures in some clinical settings. Potential for tolerance and physical dependence. May cause spasm of the sphincter of Oddi; caution with biliary tract disease, including acute pancreatitis. May cause increases in serum amylase level. Not recommended for use during or immediately prior to labor. May impair mental/physical abilities.

ADVERSE REACTIONS

Respiratory depression/arrest, circulatory depression, cardiac arrest, hypotension, shock, N/V, constipation, headache, pruritus, insomnia, dizziness, asthenia, somnolence.

DRUG INTERACTIONS

CYP2D6 inhibitors may block the partial metabolism to oxymorphone. May enhance neuromuscular blocking action of skeletal muscle relaxants and increase respiratory depression. Additive CNS depression with other CNS depressants (eg, narcotics, general anesthetics, tranquilizers, alcohol); when combination is contemplated, reduce dose of one or both agents. Mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, buprenorphine) may reduce analgesic effect and/or precipitate withdrawal symptoms. Not recommended with MAOIs or within 14 days of stopping such treatment. May cause severe hypotension with phenothiazines or other agents that compromise vasomotor tone. Muscle relaxants (eg, cyclobenzaprine), MAOIs (eg, phenelzine), and antidepressants (eg, TCAs, SSRIs, SNRIs) may enhance serotonergic activity, resulting in the development of serotonin syndrome.

PREGNANCY AND LACTATION

Category B, not for use in nursing.

MECHANISM OF ACTION

Opioid analgesic; pure opioid agonist. Has not been established. Specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and play a role in analgesic effects.

PHARMACOKINETICS

Absorption: Absolute bioavailability (60-87%). Administration of multiple doses resulted in different parameters. **Distribution:** V_d=2.6L/kg (IV); plasma protein binding (45%); found in breast milk. **Metabolism:** Extensively metabolized to noroxycodone (major metabolite), oxymorphone (via CYP2D6), and their glucuronides. **Elimination:** Urine; $T_{1/2}$=3.5-4 hrs.

ASSESSMENT

Assess for level of pain intensity, type of pain, patient's general condition and medical status, or any other conditions where treatment is contraindicated or cautioned. Assess for drug hypersensitivity, renal/hepatic/pulmonary impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of respiratory depression, hypotension, convulsions/seizures, spasm of the sphincter of Oddi, increases in serum amylase levels, tolerance, physical dependence, and other adverse reactions. Reassess the continued need for therapy.

PATIENT COUNSELING

Advise to report episodes of breakthrough pain and adverse experiences occurring during therapy. Instruct to not adjust the dose without consulting physician. Inform that drug may impair mental/physical abilities required for the performance of potentially hazardous tasks. Counsel to avoid alcohol or other CNS depressants, except by the order of physician. Advise to consult physician regarding effects when used during pregnancy. Inform that drug has potential for abuse and should be protected from theft and never be given to anyone other than for whom it was prescribed. Counsel that if taking medication for more than a few weeks and need to d/c therapy, to avoid abrupt withdrawal, as dosing will need to be tapered.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from moisture.

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